

(Tentative Translation)

**Report from the Government of Japan**

**Concerning the Recommendations**

**from the EU-Japan Business Round Table (BRT)**

April 2013

Note: The content of this report is based on the situation as of December 31, 2012.

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## **Working Party A: Trade Relations, Investment and Regulatory Cooperation**

### **1. Strengthening the EU-Japan Economic Relationship (WP-A/#01/EJ to EJ)**

#### **BRT Recommendation**

The BRT calls on the European Commission and the government of Japan to expedite the remaining efforts necessary to complete their scoping activities on ambitious terms. The BRT also urges the European Commission and the Council of the EU to expedite their respective work on the mandates to authorise the European Commission to negotiate an FTA/EPA and a political and cooperation agreement with Japan on the basis of a successful scoping and keeping in mind the high level of ambition shown at the May 2011 EU-Japan Summit and supported by the BRT in its September 2011 "Joint Statement Towards an EU-Japan FTA/EPA". An ambitious, balanced and mutually beneficial FTA/EPA would have to be comprehensive and tackle major outstanding issues, such as tariffs, non-tariff barriers, public procurement, investment, and harmonisation/mutual recognition of regulations and standards, to develop and unlock the growth potential of EU-Japan economic relations.

#### **< Background >**

As major advanced economies and major global traders and investors, the EU and Japan can do more to unlock the enormous growth potential which their bilateral economic relations can offer. They are now working on enhancing bilateral trade, investment and cooperation and building a closer relationship. As both strive to overcome global financial instability and economic uncertainties, it is crucial that they join forces in tackling common challenges in order to attain a long-term, sound and stronger growth.

#### **Action taken so far**

Based on the agreement at the 20th Japan-EU Summit in May, 2011, the Government of Japan and the European Commission conducted the scoping exercise which defined the scope of the future Japan-EU EPA negotiations. Following the conclusion of the scoping exercise, the European Commission decided to ask the Council (Member States) for a mandate to start negotiations on July 18, 2012. The Foreign Affairs Council of the EU adopted the negotiating mandates for a Japan-EU EPA on November 29, 2012. With this decision by the Foreign Affairs Council, the European Commission obtained the negotiating mandate for the Japan-EU EPA, which clears the path for the launch of negotiations between Japan and the EU.

#### **Future outlook**

Given the potential of the Japan-EU EPA to contribute to economic growth of both sides, Japan will continue to work towards a high level EPA with the EU. Negotiations are to start in due course in 2013.

2. Call for a breakthrough in WTO Doha Development Agenda negotiation and statement of strong support for fight against protectionism (WP-A/#02/EJ to EJ)

#### BRT Recommendation

The BRT is a strong supporter of the multilateral trading system, whose core functions are: trade liberalisation, rule-making and dispute settlement. However, the initial high level of ambition of the Doha Round, launched in 2001, has not been confirmed resulting in the current deadlock of negotiations. A so-called “Plan B” was abandoned in May 2011. Also the December 2011 8th Ministerial Conference in Geneva could not overcome the current deadlock which has revolved both around a lack of political will and the inability to bridge the gap of market access commitments between OECD and emerging country members.

With the prospects of great uncertainty, the WTO must demonstrate its ability to deliver results for the business community. It should focus more on its core functions in the future, namely trade liberalisation and rule making. As the only international organisation creating rules and setting standards on trade at the multilateral level, the WTO must remain leader in this area and take more action. The existing legal framework provides an excellent basis but needs to be updated in order to respond to a changing global economic landscape.

Ambitious agreements on trade facilitation and non-tariff barriers should be concluded quickly. This would provide a significant boost to international trade. In addition, plurilateral sectoral agreements should be further negotiated. The WTO should also work towards clearer WTO guidelines on the coherence between bilateral / regional trade agreements and the WTO system. Finally, the WTO should explore other topical issues, such as the relationship between trade and investment, competition, energy and raw materials.

By advancing on a case by case basis the WTO should demonstrate its ability to develop new trade rules and help its members see the advantages of trade liberalisation. This should then serve to allow the restart of more comprehensive market access negotiations. Any weakening of the multilateral trade system should be prevented by all means.

#### Action taken so far

With regard to the Doha Development Agenda, Japan is continuously committed to exploring different negotiating approaches while respecting the principles of transparency and inclusiveness, in line with the outcome of the Eighth Ministerial Conference in December 2011.

Japan welcomes the recent progress in specific areas such as trade facilitation, expansion of ITA product coverage and membership and further liberalization of trade in services. Regarding trade facilitation, Japan continues to play a constructive role in advancing the negotiations for more simplified and reasonable trade procedures as well as more transparent, predictable and consistent administration of trade regulations. Japan has dedicated itself to the ongoing discussions on the expansion of ITA product coverage and membership. Japan has been participating in the plurilateral initiative over the past several months with other voluntary WTO members for a possible ambitious services agreement, and the participating members confirmed that they would aim to secure domestic

authority to commence negotiations as early as possible in 2013.

Regarding resisting protectionism, at the G20 Los Cabos Summit and the APEC in Vladivostok in 2012, the members reaffirmed their commitments to standstill, refraining from imposing new export restrictions, and roll back protectionist measures and issued a strong message for resisting protectionism.

#### Future outlook

With regard to Doha Round negotiations, based on the outcome of the Eighth Ministerial Conference, the GOJ will continue playing an active role in the negotiation.

Further, Japan will work to strengthen and improve the functioning of the WTO including that of the dispute settlement and of enhancing transparency of trade policies.

In particular, with regard to resisting protectionism, Japan will continue to make contributions in maintaining and strengthening monitoring system through the WTO.

### 3. Applying international standards and enhanced cooperation in the promotion of new global standards (WP-A/#03/EJ to EJ, WP-A/#07/E to J)

The BRT urges both authorities to adopt international product standards and certification procedures where applicable, and, to promote harmonisation of standards and certification procedures, mutual recognition of product certification and, when possible, and appropriate, mutual acceptance of functionally equivalent regulations governing the application process for importing and selling/using products in sectors such as Construction Materials, Organic Products, Cosmetics, Medical Devices, Veterinary Products, Automobiles and Processed Food.

#### (1-1) Construction materials

##### BRT Recommendation

The Government of Japan should work together with the EU Authorities towards mutual recognition of all JAS/JIS and EN standards for all building materials. Procedures for foreign testing institutes seeking accreditation under JAS/JIS should be streamlined. Mere reference to ISO standards within JAS/JIS, has proved not to be adequately helpful in facilitating the process.

The BRT also calls for Japan to lower its threshold for construction services procured by sub-central Governments and public enterprises to 5,000,000 special drawing rights.

##### Action taken so far

#### (1)JAS/JIS

It is already possible for a foreign institute to be registered as a Registered Overseas Certifying Body (JAS) or a Foreign Accredited Certification Body (JIS) following a review of the required documentation and an on-site inspection. Moreover, registration is based on ISO/IEC 17065, an internationally recognized accreditation standard. In other words, we do not believe that we are imposing particularly difficult requirements for registration.

#### (2)Government procurement

In December 2011, the negotiation of the revision of the WTO Agreement on Government Procurement (GPA) was concluded. As a result of the negotiation, all GPA members including the EU agreed on Japan's maintaining the threshold for the procurement of construction services at the same level as the present GPA.

##### Future outlook

#### (1)JAS/JIS

We intend to continue to ensure that the accreditation system is appropriate, explaining it to foreign institutes whenever the need arises.

#### (2)Government procurement

N.A.



## (1-2) Organic products

### BRT Recommendation

The Government of Japan should work together with the EU authorities to achieve true mutual recognition of Organic Food Products labelling. Currently, products which are certified as organic in Europe and meet the organic-JAS regulations and are labelled organic in Japan must obtain a supplementary organic certificate from the Embassy of the country of origin every time they are imported into Japan. The BRT requests the abolishment of this need for supplementary organic certificates. The BRT recognises the work of the Cabinet Office in this regard and is looking forward to see the result of this work.

### Action taken so far

In June 2010, the EU recognised the organic JAS system as equivalent to the EU's counterpart, and consequently the equivalence recognition of organic rules and standards between Japan and the EU became mutual. Both parties have been taking necessary measures to maintain the credibility of the organic products. When Japan imports products which are certified as organic in Europe, the Government of Japan (GOJ) does not require a supplementary organic certificate issued by the Embassy of the country of origin, but requires the necessary certificate to confirm organic certification issued in the country of origin.

### Future outlook

The GOJ intends to closely cooperate with the EU in ensuring the integrity of organic labelling.

### (1-3) Cosmetics

#### BRT Recommendation

European cosmetics firms find it continuously difficult to expand their business in Japan due to the difference in standards for ingredients and permitted efficacy claims between Japan and the EU and the Japan-specific product certification procedures for so-called quasi drugs. The BRT calls for common regulations on the certification of medicated cosmetics, so-called quasi drugs (disclosure of approved ingredients, standard application times); common regulations on efficacy claims and advertisements; a common positive list of allowable ingredients in cosmetics; and establishment of joint standards for alternatives to animal testing.

#### Action taken so far

The Government of Japan (GOJ) has developed and published the positive list of active ingredients and additives for so-called “medicated cosmetics”, which are classified as quasi-drugs under Pharmaceutical Affairs Law. On the 21<sup>st</sup> July, 2011, “minimizing the appearance of fine lines due to dryness” was added as No.56 of cosmetic efficacy claims to the list of the scope of cosmetic efficacy.

Furthermore, the Ministry of Health, Labour and Welfare, together with the Pharmaceuticals and Medical Devices Agency (PMDA), have had timely meetings with the industry to exchange views on rapid review process of quasi-drugs.

Regarding the alternative testing methods, the GOJ has already accepted not only the OECD –adopted alternative animal testing methods but also alternative animal testing methods validated by JaCVAM (Japanese Center for the Validation of Alternative Methods), in cooperation with validation centers of the EU, the United States, Canada, and Korea under the framework of ICATM (International Cooperation on Alternative Test Methods) .

#### Future outlook

The GOJ will continue to exchange views with the industry for the purpose of ensuring the transparency in approval process and rapid review on “medicated cosmetics”.

When other alternative animal testing methods, which the OECD has not adopted, are requested with appropriate data, the GOJ will validate and consider them through JaCVAM’s and other activities.

#### (1-4) Medical devices

##### BRT Recommendation

The EU's export of medical devices to Japan is limited by the costly and cumbersome approval process. Development costs for EU medical device producers are increased by requests for additional clinical trials from the Japanese authorities. Excessive Japanese standards and regulatory requirements result not only in a significant device lag, but also together with the insufficient reimbursement system, a device gap. The BRT calls on the government of Japan to intensify the work to simplify and harmonise the regulatory processes in the field of Medical Devices with that of the EU. Japan needs to reduce the time and costs associated with introducing innovative new treatments in the human healthcare market in Japan and to bring Japanese rules in line with global standards.

The Government of Japan is therefore urged to create a more efficient product approval process, in particular by:

- a) Shortening the medical equipment certification process: accepting clinical trial data generated overseas and harmonising Good Clinical Practice (GCP) and Quality Management System (QMS) requirements with international standards. The BRT recommends that in the meantime, both authorities should officially recognise that either ISO 14155:2003 (and as subsequently amended) or Japan GCP is, in principle, generally acceptable to either party for all medical device clinical investigations and that, in principle, a QMS audit conducted by responsible authorities in Japan (PMDA or third party testing organisation) or by Notified Bodies in the EU is generally sufficient as evidence of compliance with quality management system requirements when applying for market authorisation on either market.
- b) Eliminating differences between Japanese GCP and the GCP established by the International Conference on Harmonisation.

##### Action taken so far

Discussions have been held since 1992 on harmonizing regulations in the medical device sector by the Global Harmonization Task Force (GHTF), which is composed of the regulatory authorities of Japan, the EU, the United States, Australia, and Canada as well as the industrial sector. In the revised Pharmaceutical Affairs Law that came into force in 2005, internationally harmonized regulations were introduced in terms of essential principles and classification of devices. In addition, with regard to the establishment of Approval Standards, Certification Standards and standards for Quality Management Systems, the Government of Japan (GOJ) basically accepts the international standards of the ISO and the IEC.

Foreign clinical trial data has been accepted as a part of application dossier when: i) standards for conducting medical device clinical trials are set by the regulations of the country or region where the trial was performed, ii) the standards are equivalent or surpass the Japanese medical device GCP, and iii) the clinical trial was conducted in accordance with the standards or considered to have equivalent

level of quality.

For the purpose of reducing the industry's burden and promoting the efficiency of inspection, through the solution of a few specific non-tariff issues (called "Paragraph 34 process"), the GOJ agreed to align Japanese QMS standard for medical devices with the international standard(ISO13485), which is applied in the EU, but with some exceptions.

The GOJ is making efforts to clarify GCP operations through various notices and Q&A. Based on the Five-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices, the GOJ also worked on improvements of GCP operation. In April 2009, the ministerial ordinances relating to clinical review board, notification of clinical trials, delivery of investigational devices and others were revised in order to be consistent with the ICH-GCP. The GOJ therefore thinks that Japanese GCP is harmonized with ICH-GCP in principle.

#### Future outlook

Regarding acceleration of medical device review, the GOJ publicized the Action Program for Acceleration of Medical Device Review in December 2008. The GOJ is making efforts to steadily implement the Action Program in cooperation with concerned industrial sector.

The GOJ encourages active use of consultation service on individual medical device applications in advance provided by the Pharmaceuticals and Medical Devices Agency (PMDA) for use of foreign clinical trial data for application of the device.

The GOJ is discussing the revision of QMS audit system with industry groups, and planning to submit the revision of the Pharmaceutical Affairs Law to the next ordinary session of the Diet as described in "The Comprehensive Strategy for the Rebirth of Japan" and "The Next 5 Year Strategy for Medical Innovation".

The GOJ continues to discuss the global harmonization of (QMS) regulation which is necessary for the mutual recognition of QMS audit with not only between Japan and the EU, but also jointly with the U.S. and other countries through the activities in the IMDRF (International Medical Device Regulators Forum) and others, which represent a multinational initiative.

## (1-5) Veterinary products

### BRT Recommendation

Animal health products already approved in the EU have to undergo further rigorous controls and unnecessary tests before being approved in Japan, which increases costs and causes delays. Accordingly, the BRT:

- a) Urges the Government of Japan to take all measures available to speed up product approvals and fully harmonise domestic regulations with international practices.
- b) Requests Japan to work towards mutual recognition of European and Japanese marketing authorisations for veterinary products. This should start with mutual recognition of GMP certification for veterinary medicines. Harmonisation of regulations on animal vaccines, and ensuring product conformance under a unified GMP regime, should also be addressed.
- c) Asks Japan to better facilitate the use of English in applications without the need for a summary in Japanese.

### Action taken so far

Japan has been actively participating in the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and approximately 50 guidelines have been created so far. Japan has been deeply committed to the creation process and duly implemented these guidelines which resulted in reduced duplications of animal tests used as application data in the technical dossier. Moreover, Japan is actively harmonizing national regulation on veterinary medicinal products (VMP) to the international practice, e.g., seed lot system has been incorporated into its regulation for veterinary vaccine since 2008.

Japan deliberated guidance for the preparation of Summary Technical Documents (STD). This guidance provides applicants with useful advice on the preparation and, for general pharmaceutical products. Japanese translation of Technical Documents is exempted, given the STD is well-organized. Furthermore, since October 2012, Japan has extended this procedure to veterinary biologicals and antimicrobial products.

### Future outlook

Regarding VICH activities, approximately 20 guidelines are now under consideration, which will lead to further reduction of unnecessary repetitive studies.

International standards for the approval of veterinary medicinal products have not been established yet and substantial differences in the approval standards remain among Japan, the EU and the United States. In the development of international standards for approval, discussions among three VICH regions are essential. Especially, approval concepts on biotechnology based products including regenerative medicine products, and/or medical products for food animals are quite different among the regions. The three regions should start to consider further cooperation to establish an

international approval criteria based on science to mutually accept such products accordingly.

Japan wishes to import in-vitro veterinary diagnostics for infectious diseases from the EU to fill the shortage of such products in Japan. On the other hand, it takes us time to review and approve the products from the EU, because the efficacies and qualities of products marketed in the EU are not officially evaluated due to the lack of approval system for veterinary diagnostics in the EU. Japan recommends the EU industry to adopt the Japan's approval criteria and control system on a voluntary basis, and asks the EU government to implement them in the region, in order not only to accelerate the approval procedure in Japan, but also to improve the quality of the veterinary diagnostic products marketed in the EU.

The priority issue on mutual recognition of veterinary medicinal products is for both sides to mutually understand the implementation of the approval systems and consider whether mutual recognition is feasible or not. Japan believes that it is a good start for both sides to explore the possibility of launching an exchange program of officials in charge of approving veterinary medicinal products between the EU and Japan.

We would like to conclude that it is inappropriate to prioritize the mutual recognition of GMP for the time being, and recommend the EU to consider mutual cooperation after setting appropriate agendas.

## (1-6) Processed food

### BRT Recommendation

For processed food, the combination of differences between EU and Japanese standards and technical requirements as well as cumbersome border procedures results in high costs for EU exporters. The limited number of permitted food additives in Japan and unaligned standards between the EU and Japan increases costs and prevents EU exporters from utilising scale effects. High conformity costs are incurred because Japanese authorities do not accept evaluations made by the EU or international bodies. The market potential for European exporters would be greatly enhanced by:

- (a) Harmonising Japanese regulations with international standards with respect to re-dating, labelling and nutritional standards
- (b) Substantially increasing the list of permitted additives, in addition to speeding up the approval process
- (c) Introducing mutual recognition of conformity assessment procedures to eliminate the duplicate costs of evaluations.

### Action taken so far

(a)

The Japanese food labelling system which stipulates labelling methods for “use-by-date”, nutrition and other indications was reformed in 1995 as seen in the change of indication from “date of manufacture” to “use-by date,”. This amendment was adopted in order to make the system more consistent with the international standard (i.e., the General Standard for Prepackaged Foods: CODEX STAN 1-1985). Based on the internationally unified standards such as CODEX standards, the Japanese food labelling system is considered to be consistent with the international standards.

(b) & (c)

The Food Sanitation Law prohibits the use of food additives in Japan except when they are designated under the law by the Minister of Health, Labour and Welfare (MHLW) as substances that are unlikely to pose a risk to people’s health. The procedure of designation for food additives, as defined above, is initiated based on an application filed by a business or relevant person. The Government of Japan (GOJ) understands that the EU follows a similar system for the authorization of food additives.

MHLW makes utmost effort to streamline the designation process for food additives, which is a big concern of the EU. Specifically, MHLW facilitates communication with the Food Safety Commission (FSC), a risk assessment body, makes efficient clerical work needed before safety assessment is requested to FSC, and cooperates with FSC so that assessment can be carried out in a more speedy manner.

As for sunflower lecithin, which is one of EU industries' concerns, MHLW already submitted the request to FSC for the assessment in March 2012 and it is under discussion of the Experts Committee of FSC.

Since 2002, the GOJ, on its own initiative, has been proceeding with discussions towards the designation concerning the 45 food additives (excluding flavorings), including substances requested by the EU, whose safety has been confirmed internationally and are widely used.

In September 2012, the GOJ drew up and published the roadmap for the designation of the 15 non-approved substances based on the Cabinet decision made in July 2012 to designate them within around one year, excluding time required for collecting additional information requested by the FSC. Subsequently, two substances were designated in November, 2012 and in January, 2013 respectively. As for 3 of the remaining 13, MHLW is proceeding with formalities for designation.

The remaining 10 are under discussion of the Experts Committee of FSC.

#### Future outlook

(a)

We continue to operate the system in accordance with the international standard.

(b)&(c)

Substances for which MHLW is proceeding with formalities for designation are the following three: isopropanol, potassium lactate, and potassium sulfate. Potassium lactate and potassium sulfate are under review by the Pharmaceutical Affairs and Food Sanitation Council and MHLW will soon take the necessary procedures, including the WTO notification. Isopropanol is at the stage of preparation for discussion by the Council. As for the remaining 10 and sunflower lecithin, which are under discussion of the Experts Committee of FSC, MHLW will initiate formalities for designation as soon as assessment is completed. MHLW will continue to work to accelerate the designation process that has been carried out until now.

In 2002 MHLW listed the 45 substances with the intent to designate them. At that time, these substances were already proven safe by JECFA and being widely used in many countries including the EU member states and the United States. MHLW took the opinions of the EU and the US into consideration in the listing work. The GOJ believes that when the designation of the 45 substances almost cover the food additives whose need is globally recognized.

Japan's action for the 45 substances is a special measure taken to ensure international consistency. The GOJ will follow the ordinary process for designation of substances beyond these 45, based on applications from businesses, as other major countries do.



## (2) Global patent

### BRT Recommendation

The BRT recognises the importance of global patent harmonisation and streamlining of the patent system as a way to promote innovation, reduce costs and boost legal certainty. The authorities of the EU and Japan should take the lead in these efforts.

### Action taken so far

At the framework of the IP5 offices including the Japan Patent Office (JPO) and the European Patent Office (EPO), a comparative study of laws and practices was conducted. The IP5 offices agreed to hold discussions of patent harmonization based on the results of the study at the newly established patent harmonization expert panel. In addition, the Tegernsee Group, consisting of IP offices in Japan, the United States, major European countries and the EPO, conducted in-depth studies on several important issues regarding patent harmonization. The Tegernsee Group agreed to conduct consultations with users as the next step.

At the same time, the JPO and the European IP offices are making efforts to expand the framework of Patent Prosecution Highway (PPH), in order to streamline patent examination practices. In 2012, the JPO launched a pilot program with a number of countries and regions, including Portugal.

### Future outlook

The Government of Japan (GOJ) will promote discussions on patent harmonization at various forums such as the IP5 and Tegernsee Group meetings, while obtaining users' opinions on patent harmonization.

As for the PPH, the GOJ will advance the discussions towards the simplification and standardization of PPH application procedures with the PPH-participating countries as well as encourage emerging countries to participate in the PPH program.

### (3) Energy conservation, relevant labelling rules and carbon footprint schemes

#### BRT Recommendation

Given the nature of the issue and the importance for business as well as for society in general, the two Authorities should make an effort to harmonise the regulations for energy conservation, relevant labelling rules, and carbon footprint schemes.

#### Action taken so far

The energy-saving labelling system introduced by the Government of Japan (GOJ), which mainly focuses on household products, currently covers 18 items.

Furthermore, the GOJ has launched the labelling system for retailers. It stipulates that retailers shall provide information of appliances displayed at their shops with the use of 'Uniform Energy-Saving Label' which displays a multistage rating of the given product. 5 products are covered currently.

The pilot project of Carbon Footprint of Products (CFP), which the GOJ had conducted since 2009, finished in March 2012. As achievements of the project, 73 Product Category Rules (PCRs) were developed and 469 CFPs were verified. After the transition period, the CFP project has been carried out by the private sector since July 2012.

#### Future outlook

In addition to reviewing the multistage rating standard, the GOJ will continue to expand coverage of the labelling scheme for manufacturers and the unified labels for retailers. The GOJ will also distribute PR materials to enhance the recognition of labeling.

Japanese CFP pilot project has been promoted along harmonizing with international standards such as the ISO to transfer private sector. The GOJ will continue to ensure that the system is consistent with international standards including the ISO.

#### (4) AEOs (Authorized Economic Operators)

##### BRT Recommendation

Following the agreement on the mutual recognition of the AEOs (Authorized Economic Operators) in June 2010 between the EU and Japan, the Authorities of the EU and Japan should aim at introducing further regulatory cooperation in order to give more concrete benefits to AEOs. The BRT would in this regard like to put emphasis on simplifications of import procedures where companies are given a greater freedom while also taking greater responsibility for their imports.

##### Action taken so far

Mutual recognition of the AEOs between the EU and Japan has been steadily implemented since May 2011. Based on the mutual recognition, AEOs in Japan and the EU have received benefits in customs procedures of the other side. In order to enhance the regulatory cooperation between Japan and the EU, the 5th Japan-EU Joint Customs Cooperation Committee was held in Brussels in June 2012. The Customs Authorities of the EU and Japan confirmed the progress made regarding the mutual recognition, and agreed that potential further benefits for reliable traders should be discussed.

##### Future outlook

With respect to the mutual recognition of the AEOs between Japan and EU, in addition to the continuous review of its implementation, the Customs Authorities of Japan and the EU will discuss the additional benefits to be granted to the AEOs.

(5) Development of practical application of new technologies (RFID, etc.) ,(6) Dissemination of model ICT use

#### BRT Recommendation

The two Authorities should create a framework between the EU and Japan in the development of practical application of new technologies, such as RFID and biometrics authentication technologies. This will enable and enhance cooperation among companies in the EU and Japan, and will also promote new international standardisation and lead to its dissemination.

The two Authorities should disseminate model ICT use that contributes to the security and the operational efficiency of the supply chain. For example, RFID tags, sensors, biometrics authentication technologies and UCR (Unique Consignment Reference) numbers can build a more secure and visible international supply chain.

#### Action taken so far

As one example of model ICT use, METI has been establishing a global information network, where anyone can easily share each cargo status data based on interoperable standards for optimization of global supply chain. In this regard, a recommendation to make a foothold world-level common platform was issued in May 2012.

#### Future outlook

As one example of the model ICT use, METI plans to hold a pilot project of finished-car transportation by using RFID, and then hold a seminar to introduce the measures on optimization of global supply chain based on this result.

## (7) Support for ICT for Energy Efficiency Forum

### BRT Recommendation

The European Commission and the Japanese Government should support the ICT for Energy Efficiency Forum, actively participating in it and disseminating its outcome in order to encourage global collaboration.

### Action taken so far

Japan has actively participated in ITU-T SG5 WP3 meetings and ITU symposiums for climate change in order to contribute to its standardization activities and to disseminate outcomes from Japanese activities.

ITU-T SG5 WP3 is responsible for studies on methodologies for evaluating ICT effects on climate change (e.g. GHG emission) and publishing guidelines for using ICT in eco-friendly ways. The ITU is a partner of the ICT for Energy Efficiency Forum and is processing its work in liaison with other related organizations and meetings, such as IEC, ISO, and ICT4EE Forum.

### Future outlook

Japan will continue to contribute to activities for international standardization to enhance methodologies and best practices for evaluating ICT effects on climate change. Japan will also participate in ITU symposiums for climate change in order to disseminate outcomes from the Japanese activities. Such activities would contribute to the reduction of global CO<sub>2</sub> emissions.

## (8) International harmonisation at CODEX

### BRT Recommendation

The European Commission and the Japanese Government should collaborate on achieving international harmonisation at CODEX in the description and standards for food for specified health use/functional foods.

### Action taken so far

The Government of Japan (GOJ) has been actively collaborating to achieve international harmonization through discussions on food standards and establishment of these bases in the Codex including CAC, the Codex Committee on Food Labeling and the Codex Committee on Nutrition and Foods for Special Dietary Uses.

### Future outlook

The GOJ intends to continue international cooperation through the Codex activities.

## (9) Automobiles

### BRT Recommendation

In the automobile sector, the Japanese and EU Authorities should accelerate their adoption of ECE Regulations to lower the cost of regulatory compliance for both European and Japanese automobile exporters by extending the benefits of mutual recognition. Also the Japanese and EU Authorities should work together to establish internationally harmonised technical requirements and testing procedures that will encourage the smooth market adoption of new environmentally friendly power-train technologies - electric vehicles, hybrid vehicles and fuel-cell vehicles.

### <Background >

In 1998, Japan became the first country in Asia to accede to the UN-ECE 1958 Agreement on the Mutual Recognition of Type Approval for Vehicles etc, which provides that vehicle components which have received type approval according to ECE Regulations in one contracting country are exempt from testing in any other signatory country where those regulations have been adopted. Japan has now adopted UNECE Regulations in 31 of the 45 areas included in Japanese type approval.

### Action taken so far

The Government of Japan (GOJ) has been adopting UN/ECE Regulations after the assessment of their validities and the necessary revisions of those regulations, as a part of efforts toward the realization of an International Whole Vehicle Type Approval (IWVTA) which are currently ongoing at the UN/ECE/WP29, while taking into consideration safety and environmental protection in Japan. The GOJ has been actively contributing in cooperation with the EC to promote IWVTA through such as acting as co-vice-chair of an expert meeting on IWVTA in WP29.

### Future outlook

The GOJ would continue to adopt un-adopted regulations among the UN/ECE Regulations for passenger cars, after the assessment of their validities and the necessary revisions of those regulations at the UN/ECE/WP29, as a part of efforts toward the realization of IWVTA, while taking into consideration safety and environmental protection in Japan.

#### 4. Supporting timely development of business (WP-A/#04/EJ to EJ)

##### (1) Social security contributions

###### BRT Recommendation

The BRT welcomes the conclusion of social security agreements between Japan and certain EU member states in the past, but regrets that no new agreements were concluded in 2011. Therefore, the BRT requests that, Japan and the Member States of the EU make further efforts to expand the network of Social Security Agreements. In addition, they should introduce an interim measure, by which a host country should either exempt contributions to pension funds unilaterally or refund the contributions in full when expatriates return to their home country.

###### < Background >

While individual EU Member States and Japan have concluded bilateral social security agreement, Japanese citizens in many Member States cannot use pension premiums paid in those countries towards the pension in Japan and vice versa.

###### Action taken so far

(a) The Government of Japan (GOJ) has been making efforts to conclude social security agreements with EU member states. The GOJ has already concluded social security agreements with Germany, the UK, Belgium, France, the Netherlands, the Czech Republic, Spain and Ireland, and also signed the agreement with Italy. Furthermore, the GOJ is now forwarding government-level negotiations with Hungary, Luxembourg and Sweden, and exchanges of information and opinions between the authorities with Slovakia, Austria and Finland, with the aim of concluding social security agreements.

(b) With regard to an interim measure, the GOJ has a measure in the Japanese pension system to provide benefit as a “lump-sum withdrawal payment” based on the contributions that foreign nationals have paid during their stay in case that they return to their countries after their short stay in Japan.

###### Future outlook

The GOJ intends to continuously proceed negotiations as well as exchanges of information and opinions with a view to concluding of social security agreements with European countries.



## (2) Personal data protection regime

### BRT Recommendation

The BRT believes that the ultimate objective of personal data protection for an individual business is to adopt and implement a reliable and cost-effective personal data protection system at the level of a corporate group, within which the flow of data should be free across national borders. In order to achieve this, the national legislation of each country should promote such a system rather than impede by creating different requirements.

To realise such a business environment between the EU and Japan, the Government of Japan should make sure to build on the report of July 2011 of the Special Commission about Personal Information Protection established in the Consumer Commission with a view to realise a harmonised data protection regime between the EU and Japan. Furthermore, the EU has launched the legislative process of significantly modifying its Directive 95/46/EC. The two authorities should consult closely with each other so that the two regimes should not become more diverse.. The two governments should then launch the adequacy-finding procedure under the EU Directive as soon as feasible.

In parallel with the above process, the authorities of the EU and Japan should launch a dialogue in order to seek an international framework by enhancing cooperation with third countries and international organisations. It should eventually lead to the closer alignment of data protection regimes around the world that would enable global businesses to transfer personal data by complying with one regime.

In addition, the authorities of the EU and Japan should improve legal certainty surrounding the use of new technological tools such as cloud computing applications and services. The BRT believes that such improved legal certainty would support and enhance the application of new technological developments while maintaining the degree of data protection currently provided.

### <Background>

Implementation of these recommendations will lead to a significant improvement in the personal data protection regimes of both the EU and Japan.

### Action taken so far

(a) In Japan, the Act on the Protection of Personal Information was passed in May 2003 and all its provisions came into effect in April 2005. Although it has been modified somewhat to reflect realities in Japan, the provisions concerning the obligations of entities handling personal information are based on the eight principles contained in the OECD guidelines issued in 1980. Enforcement authority of the act is entrusted to each minister in charge of the business sector concerned, and based on guidelines determined by each minister, the precise interpretation, application and appropriate enforcement is conducted.

Until now, our efforts to safeguard personal information have been made in light of international initiatives by organisations such as the OECD, APEC, the EU, ICDPPC, and APPA, and in April 2008 we partially revised our Basic Policy on the protection of personal information in order to respond to these international initiatives and better safeguard the rights and interests of consumers. Based on this Basic Policy, in November 2011, each ministry and agency participated in "APEC Cross-border Privacy Enforcement Arrangement". And with regard to the guidelines for each business sector, new guidelines have been established and existing ones have been revised when necessary. Through such efforts, personal information is being effectively safeguarded.

In July 2011, the Special Commission on Personal Information Protection established in the Consumer Commission published "the Report of the Special Commission on Personal Information Protection" (hereunder "the Report"). In the item of international consistency (part2-4) of the Report, the Special Commission mentions, "In the field of international consistency of the system about the personal information protection, it is important to promote understanding of the international community about the legal system in Japan and consider how to coordinate with them, taking into account of the needs of business entities acting outside of Japan".

(b)Refer to the response about the cloud computing of WP-C/#7/EJ to EJ.

#### Future outlook

(a)Personal information will continue to be safeguarded at an appropriate international level through efforts to ensure the efficiency of the rules based on the Act on the Protection of Personal Information, our basic policy on the protection of personal information (partially revised on April 25, 2008), and the guidelines set by each ministry. In addition, the Special Commission about Personal Information Protection in the Consumer Commission has been discussing the problem of personal data protection, which does not exclude the possibility of the review of the Act, and the Special Commission submitted the Report to the Consumer Commission. The Consumer Commission expressed their recognition that the problems raised in the report are important, and need to be considered continuously. The Government of Japan will take into consideration the discussion of the Consumer Commission when we formulate our policy on personal information protection.

(b)Refer to the response about the cloud computing of WP-C/#7/EJ to EJ.

## 5. Better regulation (WP-A/#05/EJ to EJ)

### BRT Recommendation

The BRT recommends that Japanese and European policy-makers increase mutual understanding of existing and upcoming regulations on each side and their impact on foreign business to exclude unwittingly taking initiatives that create barriers to trade. Both sides should commit to exchanging annual legislative work programmes at the earliest stage to prevent regulatory divergence and new trade barriers. In addition, the two sides should agree to an early warning system for draft legislation in order to make the dialogue effective. The EU and Japan should also develop a joint strategy to promote better regulation, learning from each other's experience and adopting a common system of good governance. Currently the views of businesses in Japan and the EU are not sufficiently taken into account in the regulatory process.

### < Background >

Better regulation, based on transparency, early public consultation, impact assessment, public access to draft regulations or administrative measures, could lead to a reduction in the cost of regulatory compliance and the overall administrative burden, which would be to the benefit of the Japanese and European economies as a whole.

### Action taken so far

Each Administrative Organ has been legally obligated to conduct ex-ante evaluation of regulations since October 1, 2007. In addition to this, in August 2007, the Ministry of Internal Affairs and Communications (MIC) formulated the "Implementation Guidelines for ex-ante Evaluation of Regulations" that provides standard guidance for what kind of analysis should be conducted, what procedures are necessary and other related matters, in order to promote smooth and effective implementation of ex-ante evaluation of regulations. Since then, MIC has made efforts to have the RIA accepted by administrative organs as the method of ex-ante evaluation of regulation so that it would achieve the intended effect.

In addition, in order to review existing regulations and institutions, the Committee on Regulatory and Institutional Reform (formerly known as "the Subcommittee on Regulatory and Institutional Reform") was established under the Government Revitalization Unit in March 2010, and since then the Committee has encouraged responsible ministries to review their regulations and institutions. Over three sessions of activities by the Committee, cabinet decisions were made on approximately 480 items in total. Further, in August 2012, the Committee launched its fourth session, which culminated in the cabinet decision on 70 items conducive to economic recovery in November 2012.

### Future outlook

As for regulatory and institutional reform, the Committee will reach and publish its conclusions around June 2013.

## 6. Support for SMEs (WP-A/#06/EJ toEJ)

### BRT Recommendation

The BRT calls on the EU and Japanese Authorities to develop measures to promote and assist SMEs to explore and seize business opportunities in each other's market. Should negotiations for an FTA/EPA begin, specific consideration should be made to establish measures for SMEs within the framework of negotiations.

### < Background >

SMEs are considered as new sources of growth and jobs in both Europe and Japan and “going international” is one factor for enhancing their growth potential. Promoting SMEs' internationalisation is becoming increasingly important as a policy priority in the EU and Japan. In this context it should be noted that the market access problems and other impediments underlined in the BRT recommendations can be even more difficult to tackle or manage for SMEs. With this background the BRT considers it important for the EU and Japanese Authorities to discuss and cooperate to introduce support measures (e.g. grants, tax incentives), or improve existing measures (e.g. through exchanges of best practices), to help EU and Japanese SMEs seize business opportunities in each other's market.

### Action taken so far

It is important to support cross-border business activities of SMEs. With a view to supporting foreign SMEs which consider investing in Japan, JETRO has been providing various forms of assistance such as improving necessary business information providing service, and individual consultations with experts on a case-by-case basis. In addition, we have actively contributed to the authorities' discussions on fostering SMEs' participation in global markets, through giving a presentation of the GOJ's measures, in the Working Party of OECD.

### Future outlook

Amid growing SMEs' interest in overseas business expansion, we will continue to improve support measures and strengthen our support system. In addition, the GOJ and the EU will explore the possibility of bilateral cooperation that benefits SMEs in the context of the Japan-EU EPA negotiations.

## **Working Party B: Life Sciences and Biotechnologies, Healthcare and Well-being**

### 1. Formulation and steady implementation of action plans for “The Strategy for Rebirth of Japan” (WP-B/#29/J to J)

#### **BRT Recommendation**

The Japanese government should finalize concrete action plans for promotion of R&D and faster applications in LS & BT fields.

#### **<Background>**

In “The Basic Policy for Rebirth of Japan”, which the council on National Strategy and policy is compiling, the Japanese government shows the flag for creation of new industries and markets which adapt to the environmental changes to reinforce Japan’s growth potentials. The Japanese government especially refers to draw up amid-term strategy to realize “Japan as a forefront runner in the world” in the fields of development of new drugs, medical devices, regenerative medicines and personalized healthcare. Therefore, focused measures on life innovation fields should be included in “The Strategy for Rebirth of Japan”, which will be finalized by June 2012.

#### **Action taken so far**

Based on the Five-Year Strategy for Health Care Innovation (Decided by the Health Care Innovation Council in June, 2012), the Government of Japan (GOJ) made a cabinet decision on the “Comprehensive Strategy for the Rebirth of Japan” in July, in which health and life science was identified as one of its priority areas. Health and life science growth strategy included in the Strategy consists of the following four principle pillars; “creation of innovative drugs and medical devices,” “regenerative medicine,” “personalized medicine,” and “robots and peripheral services for medical and long-term care.” In accordance with this Strategy, the GOJ will implement such policy measures as creation of the Academia-Industry-Government Network for Drug Discovery Research for creation of innovative drugs and medical devices, development of core hospitals for clinical researches with ARO (Academic Research Organization) functions, continuing support for researches on iPS cells and other globally advanced technologies, and examinations on submission of a bill for revising the Pharmaceutical Affairs Act to the next ordinary Diet sessions (in fiscal 2013) for establishment of regulations and systems based on features of medical devices and regenerative medicine.

#### **Future outlook**

Through steady implementation of the Comprehensive Strategy for the Rebirth of Japan and the Five-Year Strategy for Health Care Innovation, the GOJ will promote relevant regulatory and system reforms, such as revision of the Pharmaceutical Affairs Act associated with medical devices and regenerative medicine products. It will also develop frameworks which facilitate to create innovative drugs and medical devices, regenerative medicine products, long-term care-related devices ahead of other countries through the establishment of supporting system involving all related parties from government to private sector and academia for drug creation, etc.

2.Full-fledged implementation of the new drug pricing system and abolishment of market expansion re-pricing (WP-B/#14/EJ to J)

#### BRT Recommendation

The premium for new drug creation and elimination of unapproved / off-label use drug (the premium for new drug creation) will be continued for another two years, i.e., till March 2014. It is welcomed as it supports incentives for innovative drug development, however, it is only continuation of a trial scheme. The Japanese government should finalize the implementation of the new, internationally competitive drug pricing system in Japan, , based on the industry proposal.

The abolishment of the market expansion re-pricing was not accepted by the Central Social Insurance Medical Council (Chuikyo) even though industries insisted to eliminate the system. We also urge to abolish the re-pricing rule by market expansion, which is opposite to the policy of evaluating pharmaceutical innovation.

#### <Background>

The NHI price reform proposed by the industry has been positively reviewed by the Chuikyo in December 2009 and the government decided to start a pilot implementation in April 2010. This represents a significant improvement, as it provides price stability for innovative drugs. As a compensation for this new scheme, the government will attach a system that fosters the registration of “unapproved / off-label use drugs”. Companies have received requests on developments of 181 unapproved / off-label use drugs and started forwarding those constructively.

Furthermore, companies will receive additional requests on developments of another hundreds of unapproved / off label use drugs in this year. However, in the draft for FY2012 drug pricing system reform which has been compiled in December 2011, the premium for new drug creation was determined to continue operation as a trial basis. Therefore, the conclusion brings the industry deep concerns about sustainability for evaluation of innovations. The Japanese government should implement the new premium system for innovative new drugs at the FY2014 drug pricing system revision to evaluate the companies’ efforts for elimination of the so-called drug lag in Japan and research and development of innovative new drugs.

#### Action taken so far

The premium for new drug creation and elimination of unapproved / off-label use drug (the premium for new drug creation) has been decided to continue for another two years, i.e., till March 2014 in the drug system reform in FY2012.

The Chuikyo will decide whether to continue the premium for new drug creation from April 2014 in the next drug pricing system reform, after it reviewing following factors:

- (a) Financial impact of the premium,
- (b) Development and launch of unapproved / off-label use drugs,
- (c) Development of drugs which truly contribute to improve quality of medical care in Japan, and
- (d) Utilization of generic drugs.

The market expansion re-pricing is a scheme to reduce new drug prices based on ratio of their sales expansion when their premise on pricing changes, e.g. their real amounts of sales have far exceeded their original estimations. This scheme works as an appropriate apportion mechanism of pharmaceutical expenditures under public health insurance system with limited resources considering the critical situation of the NHI, and the Chuikyo itself recognizes this scheme as essential in the drug system reform in FY2012.

#### Future outlook

The drug pricing system will be reviewed and discussed continuously for the next drug pricing system reform in the Chuikyo, giving enough consideration to the industry opinions.

### 3. Regulatory harmonization and MRA for pharmaceuticals (WP-B/#02/EJ to EJ)

#### BRT Recommendation

The regulatory harmonization and further extension of “Mutual Recognition Agreement” should be proceeded in order to avoid redundant inspections of manufacturing facilities.

In addition to oral dosage forms, API, Sterile and Bio products are being requested to apply to the MRA. The new initiative of PIC/S> PIC/S stands for "Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme, jointly refers to PIC/S". Compared to last year a strong MHLW's initiative on PIC/S has been seen. This is an agenda point for the European industry (15 countries), EFPIA and PMDA.

#### <Background>

As currently only oral solid dosage forms are included within the MRA between Japan and the EU, there are still a lot of redundant inspections of manufacturing facilities. This is not only a costly process, but it also slows down the launching of new drugs in Japan creating a significant disadvantage for Japanese patients. In order to eliminate this problem and to integrate EU-Japan economics more efficiently, harmonization of standards/guidelines and expansion of MRA should be conducted under mutual agreements. Below-mentioned are highly prioritized items for harmonization and expansion of MRA.

#### <Prioritized items for harmonization and MRA>

##### Harmonization:

- Safety measures from surveillance to vigilance should be harmonized with international standards
- Clinical development guideline and biological preparation standards for Vaccine
- Minimum Requirements for Biological Products
- Sharing knowledge and information of inspections by each regulatory authority through PIC/S

##### Mutual Recognition Agreement:

- MRA of GMP should expand to liquids, and sterile forms, API and bio products to avoid redundant inspections and testing

#### Action taken so far

Regarding safety measures of pharmaceuticals, the Government of Japan (GOJ) has been proceeding harmonization with international standards, which were developed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) as guidelines “Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting”.

Guidelines for clinical development of vaccines were published, after considering the opinion comments from industry including the European Federation of Pharmaceutical Industries and Associations (EFPIA).



The revision of the Minimum Requirements for Biological Products (MRBP) was reviewed by experts considering the comments from the industry including the EFPIA.

MHLW, PMDA and Prefectures applied to join PIC/S in March 9, 2012.

The GOJ has been discussing the MRA with the EU on occasions such as the discussion towards the negotiation of “The Japan-EU Economic Partnership Agreement”.

#### Future outlook

The GOJ is continuing the discussion of the revision of the MRBP, with hearing comments from industries including the EFPIA, as necessary.

With regard to PIC/S, the GOJ responds adequately to the review for accession approval and makes the Japanese GMP regulation more globalized through such as harmonization with PIC/S GMP guideline.

While the GOJ assigns the highest priority to enlargement of the MRA to the remaining EU countries, the GOJ is planning to discuss the enlargement of specific areas of pharmaceutical products in consideration to the schedule for discussing the MRA enlargement to the remaining EU countries.

#### 4. Mutual recognition of quality management audit results for medical devices between EU and Japan (WP-B/#04/EJ to EJ)

##### BRT Recommendation

Improve mutual recognition of quality management audit results for lower risk medical devices, e.g. those classified as Class II, ARCB under the Japanese Pharmaceutical Affairs Law, as a first step.

PMDA and MHLW should initiate to introduce a mutual recognition of quality management audit results.

##### <Background>

Based on Medical Devices Directive (MDD) of the EU and the Japanese Pharmaceutical Affairs Law (J-PAL), Quality Management System (QMS) audit results are required for each application for a license to introduce new medical devices in the market. In Europe the regular annual ISO audit results can be used for all applications during the period in which the ISO audit is valid. Recently, Japan has started to accept QMS audits at a specific manufacturing site for products with the same generic name within a one year validity of the ISO 13485 certificate. However, a number of RCBs still require submitting QMS audit results for each application. Further alignment is still necessary to reduce the burden on manufacturers.

##### Action taken so far

For the purpose of reducing the industry's burden and promoting the efficiency of inspection, through the solution of a few specific non-tariff issues (called "Paragraph 34 process"), the GOJ agreed to align Japanese QMS standard for medical devices with the international standard (ISO 13485), which is applied in the EU, but with some exceptions.

##### Future outlook

The GOJ is discussing the revision of QMS audit system with industry groups, and planning to submit the revision of the Pharmaceutical Affairs Law to the next ordinary session of the Diet as described in "The Comprehensive Strategy for the Rebirth of Japan" and "The Next 5 Year Strategy for Medical Innovation".

The GOJ continues to discuss the global harmonization of (QMS) regulation which is necessary for the mutual recognition of QMS audit with not only between Japan and the EU, but also jointly with the U.S. and other countries through the activities in the IMDRF (International Medical Device Regulators Forum) and others, which represent a multinational initiative.

5. Infrastructure improvement and international harmonization of regulation standards for approval of non-invasive diagnostic medicines and devices (WP-B/#05/EJ to EJ)

#### BRT Recommendation

Both governments should promote infrastructure improvement such as regulatory review process and structures to accelerate simultaneous research and development of therapeutic medicines and accompanying diagnostic medicines and devices (companion diagnostics).

Furthermore, both governments should harmonize each regulation on simultaneous development of therapeutic medicines and companion diagnostics, to support advancing science on personalized healthcare (PHC) based on global genome-cohort research.

#### <Background>

U.S. Food and Drug Administration (FDA) officially announced in June 2011 a draft guidance for simultaneous development of therapeutic medicines and companion diagnostics. It requires companies to develop simultaneously new therapeutic medicines and companion diagnostics which are able to stratify efficacy and safety of the new medicine.

In EU, the European Medicine Agency (EMA) has already announced a draft for adoption of genome bio-markers in clinical trials. Also in Japan, MHLW officially announced they will draft standards for regulatory approval process of companion diagnostics by FY2014.

PHC is greatly expected to be of benefit not only for government's healthcare finance but also for society and patients. To support advancing PHC, it is required to harmonize regulatory standards and to promote infrastructure improvement such as regulatory review process and structures to accelerate simultaneous research and development of therapeutic medicines and companion diagnostics.

#### Action taken so far

To accelerate research and development of therapeutic medicines and accompanying diagnostic medicines and devices (companion diagnostics), Points to Consider (PTC) is to be developed for applicants of therapeutic medicines and accompanying diagnostic medicines and devices to promote individualized medicines.

#### Future outlook

The PTC is to be published in FY 2012.

## 6. Application of GMP on medicinal gases (manufacture of medicinal gases) in Japan (WP-B/#22/E to J)

### BRT Recommendation

Reinforce the regulation for GMP on medicinal gases in Japan. MHLW has started these initiatives along with industries. But industries are protective to non-GMP facilities because of financial implications.

### <Background>

Medicinal gases are drugs or medicinal devices and have to be compliant with governmental regulations. Main regulations are national Pharmacopeia, GMP (Good Manufacturing Practices), and GDP (Good Delivery Practices). Annex 6 describes GMP and GDP for medical gases: production and distribution. The currently loose interpretation of GMP in Japan along with relatively low standards of Japanese Pharmacopeia is of lower standards as compared to those applicable in Europe or the US. We would like to suggest a reinforcement of regulations on GMP for medical gases in Japan.

### Action taken so far

With regard to the medical gas in Japan, the GOJ discussed the establishment of the industry standard with industry groups and then publicized “The Standard on Manufacturing Practice for Medical Gases” in February 13, 2012.

### Future outlook

The GOJ provides information on the standard and propagates manufacturing and quality control systems in accordance with the standard to medical gas manufacturers through prefectures.

## 7. Regulatory harmonization for animal health products (WP-B/#19/E to EJ)

### BRT Recommendation

Further harmonization and streamlining of regulatory requirements for product registration of animal health products. MAFF should start harmonization with related countries as this is the path to the 1-1-1 concept recommended previously.

### <Background>

While such global new veterinary medicinal products go already through rigorous review processes in Europe and the USA prior to registration, it requires substantial additional testing in Japan under the Pharmaceutical Affairs Law before an approval is granted. Restrictions on withdrawal period for innovative oil-adjuvant vaccines are especially stringent in Japan, and therefore, a product which is readily available to veterinarians and animal owners in Europe cannot be used in Japan. Increased harmonization of regulatory requirements would certainly improve access of animals and animal owners to innovative animal health products.

An additional important aspect is the negative impact on animal welfare: since the regulatory requirements are not harmonized, the companies are required to repeat tests on animals in Japan, even though results of identical tests are already available and are fully compliant with stringent frameworks like GLP or VICH.

### Action taken so far

Refer to the response to WP-A/#03/EJ to EJ, above.

### Future outlook

Refer to the response to WP-A/#03/EJ to EJ, above.

8. Mutual recognition of GMP and marketing authorization for animal health products (WP-B/#20/E to EJ)

BRT Recommendation

Mutual recognition of European and Japanese marketing authorizations and recognition of GMP certification for veterinary products. MAFF should work out harmonized regulations leading to the 1-1-1 concept.

<Background>

While the studies conducted under Good Laboratory Practice or Good Clinical Practice are usually accepted by the Japanese government for inclusion in the dossier, there is still no mutual recognition of Good Manufacturing Practice (GMP) for veterinary medicinal products. Moreover, any overseas production facilities that are involved in manufacture of veterinary medicinal products imported into Japan have to be accredited by MAFF even though their GMP status is authorized by European authorities. This process involves a large amount of administrative work.

In order to improve decreased speed, predictability and quality of the registration process in Japan, which were pointed out in the benchmark surveys conducted by the International Federation of Animal Health in 2007, several new steps were taken by MAFF with some progress. However, there are still delays in review process of some product segments. An EU – Japan Economic Integration Agreement should aim for mutual recognition of European and Japanese marketing authorization for veterinary products by starting off with mutual recognition of GMP certification of veterinary medicines. Harmonized regulations on animal vaccines should also be addressed under such an agreement.

Action taken so far

Refer to the response to WP-A/#03/EJ to EJ, above.

Future outlook

Refer to the response to WP-A/#03/EJ to EJ, above.

## 9. Responsible use of antibiotics in animal health (WP-B/#21/E toEJ)

### BRT Recommendation

MAFF should promote responsible use of antibiotics in animal health.

### <Background>

In common with the rest of the world, Europeans and Japanese are concerned by the development of resistance to antibiotic medicines used in human health and the potential threat that the use of antibiotics in animal health will accelerate this process. The use of antibiotics as growth promoters has been prohibited in EU since 2006. As a responsible industry, the animal health industry seeks to work with veterinarians, farmers and the feed industry to dispel the myths about the use of antibiotics in animals and promote their responsible use.

### Action taken so far

This is considered as a new recommendation.

The monitoring systems for antimicrobial resistance and use of antimicrobial agent, which are encouraged internationally, have been implemented in Japan. Risk management measures for exhaustively ensuring responsible and prudent use have been implemented in correspondence to risk assessment based on sound science. Moreover, Japan has been actively participating in international standard setting activities at OIE and Codex.

### Future outlook

In order to collect appropriate data, the current monitoring system of antimicrobial resistance will be revised to be more practically effective. Relevant risk management measures for responsible and prudent use will be continuously developed based on the risk assessment.

## 10. Support research for plant protection & biotechnology (WP-B/#18/EJ to J)

### BRT Recommendation

Support research in Plant Protection & Biotechnology

#### <Background>

Research and development of innovative and beneficial Plant Protection & Biotechnology products is key to ensure safe food supply but also to increase the efficiency and therefore, the competitiveness of the agricultural sector. To support this undertaking the governments should increase its spending for the research in Plant Protection & Biotechnology.

### Action taken so far

Since April 2008, the Ministry of Agriculture, Forestry and Fisheries (MAFF) has been implementing a five-year project to develop innovative crops that can help solve domestic as well as international problems relating to food, energy, and the environment by taking advantage of the results obtained in the previous Rice Genome Research Program, which involves the sequencing of the whole rice genome and the elucidation of the functions of agriculturally important rice genes.

To be more specific, the project aims to develop rice varieties that are resistant to disease, insects and abiotic stresses such as low temperature by using the Marker Assisted Selection.

Furthermore, the project is being undertaken to develop higher yield or quality rice varieties by making benefits from the gene-discovery researches, which identified genes and chromosomal loci regulating yield, maturity, plant shape and height, and anthesis, available for the molecular breeding.

### Future outlook

MAFF continues to conduct the project to solve both domestic and international problems relating to food, energy, and the environment in line with the plan formulated in April 2008.



## **Working Party C: Innovation, Information & Communication Technologies**

### **1. Execution of Growth strategy and ICT strategy(WP-C/#01/EJ to EJ)**

#### **BRT Recommendation**

Both Authorities should implement detailed action plans with specific targets and use PDCA cycles to monitor the status of each item. ICT Strategy Progress Reports for each action should be published on the Authorities' websites.

#### **< Background >**

The BRT welcomes both Authorities' recognition that ICT is an engine for growth and that they have designed ICT strategies that are consistent with their growth strategies. In May 2010, the EU confirmed its Digital Agenda IT strategy is an essential part in the "EU 2020" growth strategy. The Japanese Government published a New Growth Strategy in June 2010, a New Information Communication Technology Strategy in May 2010 and an implementation plan in June 2010.

#### **Action taken so far**

The Roadmaps were prepared in June 2010 and, according to the Roadmaps, the follow-ups and evaluation of undertaking and progress of each measure conducted by relevant Ministries have been carried out. The roadmaps were revised in August 2011 and July 2012.

#### **Future outlook**

Each Ministry shall implement their own measures according to the Roadmaps. Follow-ups and evaluation of undertaking and progress of each measure and revising of Roadmaps shall be conducted in the Strategic Headquarters for the Promotion of an Advanced Information and Telecommunications Network Society (IT Strategic Headquarters), whereby the implementation of PDCA cycles shall be ensured.

## 2. Coordination of trading principles of ICT services (WP-C/#02/EJ to EJ)

### BRT Recommendation

Both sides' authorities are requested to discuss trade principles of ICT services aiming at creating better environment for the business and co-operate for implementation of such principles to third countries for improving global trade conditions.

### < Background >

The European Union and The United states released a set of trade principles for information and communication technology services on 4<sup>th</sup> of Apr. 2011. Japan and the United States published similar ICT service trade principles on 25<sup>th</sup> of Jan, 2012. As ICT service sectors evolves rapidly compared to other sectors, global trading rules and regulations do not reflect and match the current landscape of this highly potential growth ICT service sector.

### Action taken so far

In order to support the overseas expansion of Japanese business in the rapidly growing ICT services sector, it is indispensable to improve the business environment by ensuring regulatory transparency in each country, preserving open networks, ensuring cross-border free flow of information and so on.

In the framework of “the U.S.-Japan Economic Harmonization Initiative,” with the United States, the Government of Japan has been considering a set of trade principles for ICT services with the view to sharing a common understanding on promoting trade in the ICT services sector such as regulatory transparency, and to encourage other countries to adopt these principles. On January 27, 2012, both governments jointly developed these principles.

Furthermore, Japan is currently negotiating with Switzerland for developing the principle. In addition, Japan is making efforts to reflect the idea of the principles on the Chapters including Electronic Commerce in EPA/FTA with other countries.

### Future outlook

We will continuously negotiate with Switzerland to develop the principles while encouraging other countries to adopt these principles through the occasion including the negotiation of WTO, EPA/FTA etc.

### 3. Building trusted and safe online environment (WP-C/#03/EJ to EJ)

#### BRT Recommendation

- (1) Both authorities should establish an information sharing / exchange mechanism between EU and Japan for cyber security
  - 1) Study on cyber-attack information sharing within closed organizations and companies.
  - 2) Study on investigation mechanism across borders.
  - 3) Study on reporting procedure for cyber-attack disclosure from companies to government (even if the personal data is included in the disclosure, companies can be exempted from breach of personal data protection.)
- (2) Study on mechanism for joint training such as simulation exercises involving both forces against cyber attack
- (3) Construction of safety network including government and defence industries.
- (4) Conduct technology development for prediction and immediate responses against cyber-attack

#### < Background >

Cyber-attacks against governments and companies are increasing recently. In this highly connected digital world, threats comes from anywhere in the world. Especially organized attack and interference targeting certain entities is a beyond control of one enterprise therefore to address this serious issue, it needs close cooperation with public and private sectors.

Enhancing trust on internet environment among societies and businesses is fundamental pillar for creation of ICT enabled new services and business models, which will lead economic growth and job creation.

#### Action taken so far

In order to ensure free distribution of information on the Internet and to respond to influences of increasing cyber attacks on socioeconomic activities, etc., strengthening of information security is highly important. Being aware of this fact, discussions were held on information security, such as talks toward building a cooperative framework on cyber fields including information security through holding the EU- Japan Internet Security Forum (November 2012) which was decided to hold by the Joint Statement regarding future comprehensive cooperation in ICT (Information And Communication Technologies) in May 2012, etc.

#### Future outlook

On the basis of “Information Security 2012” (decision at the Information Security Policy Council on July 4, 2012), etc., with a basic policy of ensuring a secure and reliable cyberspace, continuation of alliance between Japan and EU and specific measures in the same fields will continuously be examined through holding meetings, etc.

#### 4. Building robust critical infrastructure supported by ICT (WP-C/#04/EJ to EJ)

##### BRT Recommendation

Both authorities are recommended to share best practices, and earmark funding for R&D and give incentives for private sectors to construct robust resilient infrastructures supported by ICT, including telecom network and data centre, etc.

##### < Background >

Experience of the Great East Japan Earthquake on 11<sup>th</sup> of March, 2011 found out effectiveness of ICT such as social media as communication tool for emergency case, at the same time several telecommunication networks are severely damaged and service provision of fixed and mobile communication are affected because of congestion and lack of power supply. Critical infrastructures such as energy, transportation, water are supported by ICT. A robust and reliable telecommunication sector is especially important because other critical infrastructure capabilities are dependent on their connectivity. Securing connectivity is indispensable for mitigating damages at natural disasters.

##### Action taken so far

The National Information Security Center (NISC) conducted the “Study and analysis on the disaster situation of critical infrastructure information systems in the Great East Japan Earthquake,” in order to grasp the impact of the Great East Japan Earthquake on the operation of critical infrastructure information systems and its spillover effect on critical infrastructure services and, to select the issues for incorporating into the Safety Standards and BCP of critical infrastructure from the perspective of its stable operation.

The report of this study lists the measures and issues to be taken in government agencies and critical infrastructure operators regarding information systems and information transmission during emergencies and so on. These issues are being steadily proceeded in working towards consolidating critical infrastructure that is capable of responding when large-scale damage occur.

##### Future outlook

On the basis of the “Second Action Plan on information security measures for critical infrastructure” revised in April 2012, measures will be promoted such as the preparation and penetration of the Safety Standards, etc., and reinforcement of the information sharing system.

In particular, taking into consideration the lessons learnt from the multitude of damage incurred in critical infrastructure fields in the Great East Japan Earthquake and the investigation results, etc., to enable the full anticipation of risks in information security in the Business Continuity Plan (BCP), the contents of the “Guidelines for the formulation of ‘Safety Standards, etc.’ on ensuring information security in critical infrastructure (3rd edition)” will continuously be enriched.

## 5. Deployment of Next Generation Broadband Networks (WP-C/#05/EJ to EJ)

### BRT Recommendation

- (1) Regulations should provide necessary legal certainty for investors. Technologies should be able to evolve on their own merits – innovation and investment decisions should not be hampered by technology-prescriptive regulations.
- (2) Both Authorities should provide the necessary stimuli to industry to encourage the provision of high-speed fixed or mobile broadband services in the areas where deployment by private sector investment is difficult. (Such as less-populated areas).
- (3) To promote the use of ICT, both Authorities should enhance the social benefits of the next generation broadband network by encouraging education, healthcare and other government services.
- (4) To permit a more efficient use of the spectrum, and to address the very rapid traffic growth in the mobile networks due to smartphones, both Authorities should free up as many frequencies as possible for use by mobile broadband. Moreover, both Authorities should strive for a harmonised use of the spectrum to ensure economies of scale and thereby lower service prices incurred by consumers.

### < Background >

The BRT welcomes the European Digital Agenda plan to deliver fast and ultra-fast broadband in Europe. If the Agenda's goals are to be achieved, the right regulatory environment for investment and innovation is critical.

High-speed broadband networks provide the basic underlying infrastructure needed to make nearly all other services and applications of the future information society a reality. Academic research and empirical evidence have shown that a widespread and reliable broadband infrastructure will improve productivity, stimulate innovation, accelerate growth, and create jobs.

Thus, high-performance fixed and mobile telecommunications infrastructures have become decisive factors in the global competitiveness of modern knowledge-based economies. Social development, future growth and jobs will largely depend on the ability to provide for an innovation and investment-friendly regulatory framework.

Due to different subscriber density and demand in different regions and over time, different technologies and topologies are best suited for different scenarios. The principle of technology neutrality in any regulation is therefore crucial.

Innovation and investment for next generation mobile broadband are becoming increasingly critical for the above-mentioned policy objectives.

#### Action taken so far

- (1) MIC has made effort to ensure transparency and fairness in reviewing regulations in the ICT industry through holding councils and meetings open to public and following necessary procedures, such as public comment, in advance. Additionally, it endeavors to take neutral position in various technologies and always works on keeping the competitive environment in which telecommunication careers enables to roll out various services under their own business judgement.
- (2) As stated above, ICT industry is a sector to be developed by private companies in principle. But in areas in which they have difficulty investing, such as in underdeveloped areas, MIC partially provides financial support for local governments that deploy infrastructure for ultra-high-speed broadband including optical fibers.
- (3) Aiming to promote ICT utilization in the field of education, MIC has been carrying out demonstration experiments on ICT related challenges in the area of schools (the Future School Promotion Project) by creating a networking environment using tablet PCs, interactive whiteboards, and other equipment since 2010, in collaboration with the Ministry of Education, Culture, Sports, Science and Technology, As for the medical / health care sector, since 2008, in collaboration with the Ministry of Health, Labour and Welfare, and other ministries, MIC has been conducting demonstrative projects to experiment with the health information application platform (Electronic Health Record), which allows people to manage their medical and health information electronically, and realizes seamless medical services by sharing and distributing medical and health information in a secure and smooth manner.
- (4) To realize mobile broadband environment, MIC had secured frequencies in 900 MHz band for mobile phones ensuring consistency with EU. MIC has assigned the frequencies for mobile phones operator in March 2012.

#### Future outlook

- (1) (2)MIC will make effort to ensure transparency and fairness of regulations and to keep the competitive environment based on technologically neutral regulations, and continue to deploy the broadband infrastructure.
- (3)MIC continues its efforts of promoting ICT utilization by steadily implementing the above demonstration projects in collaboration with related ministries.
- (4)The ITU Radiocommunication Assembly (RA-12) completed the standardization for 4G mobile communication systems (IMT-Advanced) in January 2012. In order to facilitate the introduction of IMT-Advanced services, the frequency migration of the radio stations at the frequency range of IMT band will be completed. MIC will cooperate with EU toward the discussion of additional frequency allocation for IMT-Advanced etc., at the ITU World Radiocommunication Conference 2015 (WRC-15).

## 6. Continued efforts for ICT usage towards social challenges (WP-C/#06/EJ to EJ)

### BRT Recommendation

The BRT recommends continued efforts for the promotion of ICT use by the public sector. Both Authorities also should facilitate the convergence of ICT and other sectors, such as healthcare, education, energy and automobile etc. by budget allocation for innovative ICT demo projects. It will generate new growth service sectors for ICT industry. Where appropriate, laws and rules which could impede advanced ICT usage should be deregulated.

### < Background >

If the benefits of NGBN are to be maximised, the public sector must promote the use of ICT projects. Public sector services have a greater potential than private sector services for using ICT. Such ICT usage will drive the creation of new services and raise the efficiency of public services and contribute to solving complex societal challenges.

### Action taken so far

The Strategic Headquarters for the Promotion of an Advanced Information and Telecommunications Network Society (IT Strategic Headquarters) decided in August 2011 on “A policy pertaining to regulatory and institutional reforms in order to utilize Information and Telecommunications technology”. Concerned government ministries are engaged in implementing the reforms in line with the policy and IT Strategic Headquarters followed up the progress of each policy in July 2012.

Concerned ministries have been undertaking demo projects and also examine institutional matters in order to facilitate utilization of a wide variety of information in large quantities ("big data") and integration of various fields through use of ICT.

### Future outlook

The Planning Committee, under IT Strategic Headquarters, chaired by Minister of State for Science and Technology Policy, will continually follow up the progress of the reforms in line with the policy and report the progress to IT Strategic Headquarters.

Furthermore, discussion on institutional matters and demo projects will be continued.

7. Balanced approach of personal data protection and innovation in the cloud computing era (WP-C/#07/EJ to EJ)

BRT Recommendation

- (1) The BRT welcomes the fact that the European Commission is proposing a Regulation as the legal instrument for aiming higher level of the harmonization of data protection within the EU. It will lead to innovative new online services across Europe. The BRT also welcomes the inclusion in the proposal of a consistency mechanism for ensuring coherent implementation among Member States and of the explicit legal recognition of Binding Corporate Rules (BCRs)
- (2) However, the current proposal contains several clauses that are difficult to implement and that increase administrative burden for businesses. The European Commission is requested to discuss with global businesses a practical implementation ensuring innovation and privacy protection and that will finally create benefit for consumers in Europe. Further clarification is required for the definition of personal data, modality of consent, data portability, right to be forgotten, data breach notification procedure and sanctions. Introduction of penalty amounts to the maximum 2% of company's worldwide turnover is excessive comparing the gravity of breach. Further simplification of BCRs should also be considered.
- (3) The Government of Japan is reviewing its Personal Data Protection law in its Consumer Commission. The two authorities should consult closely with each other so that the international data transfer regime between the EU and Japan should become streamlined so as to develop a better environment for businesses. Both Authorities should then launch the adequacy finding procedure to enable data transfer from the EU to Japan as soon as feasible.
- (4) Both Authorities should review regulations prohibiting applications from using cloud computing. When reviewing regulations, proper utilization of big data should be considered.
- (5) The EU and Japanese Authorities should begin a cloud computing dialogue to harmonise regulations on cloud computing and thereby facilitate cross border transactions and international data transfers within the EU and between the EU and Japan while enhancing the balance of privacy, information security against cyber-attack, data protection and the free flow of information.

< Background >

The European Commission proposed General Data Protection Regulation on 25<sup>th</sup> of Jan, 2012. This is a fundamental reform of EU data protection framework after Directive.95/46/EC

Action taken so far

- With regard to BCR, it was stated in the APEC Joint Ministerial Statement as follows: "We look forward to implementation of the CBPR, including through discussion on the issues of comparability and potential interoperability between the European Union Binding Corporate



Rules and APEC CBPR System."

- In July 2011, the Special Commission on Personal Information Protection established in the Consumer Commission published "the Report of the Special Commission on Personal Information Protection" (hereunder "the Report"). In the item of international consistency (part2-4) of the Report, the Special Commission mentions: "In the field of international consistency of the system about the personal information protection, it is important to promote understanding of the international community about legal system in Japan and consider how to coordinate with them, taking into account of the needs of business entities acting outside of Japan".
- With regard to cloud computing, the Ministry of Internal Affairs and Communication is making efforts to create a secure and safe environment for cloud-service use on the basis of "the Smart Cloud Strategy" announced in May 2010. In addition, the Ad-hoc Group was established under the Basic Strategy Board of the Information and Communications Council and it has reported the present status, problems and direction with regard to the utilization of big data (May 2012). In order to consider measures aimed at promoting use and flow of "personal data" (information about an individual) on the network, which take into account internationally harmonized privacy protection, etc., "Study Group on use and flow of personal data" has been held (established in October 2012).
- In order to promote a safe and secure cloud computing for increasing the competitiveness of Japanese industry encouraged by energy-saving and innovation, the Ministry of Economy, Trade and Industry (METI) launched the "Growth strategy of the Japanese economy driven by cloud computing" in August 2010. According to the above strategy, METI is engaged on development of institutions and technologies for reliability and energy-saving, privacy-conscious anonymity, and transparency of cloud service quality. In addition, in order to create new industry by utilizing wide variety of information in large quantities and, METI established "IT integration forum" that consists of working groups, which examines the cross-sectoral themes for information utilization, and project groups, which sorts out of concrete problem through discussion on creating data-driven possible new services. As for the working groups, METI has established "Personal Data Working Group", in which METI seeks to balance the economic value and privacy protection through discussion on establishing the ways of building trusts between individuals and service providers and on non nominal, practically significant, "privacy policy" and/or "terms of use" as the first touch point where individuals contact service providers. In each project group, based on data of specific area such as probe data and manufacturing data, possible business models utilizing data are being discussed. Once concrete problems are clarified, they would be passed to working groups and be discussed toward the resolution of such issues. Moreover, METI has allocated budget on projects that aim to research and develop system and sensor technologies that are going to be necessary for creating data driven new industry.
- A technical seminar was held in Tokyo in April 2012 to exchange information and views on cloud computing policy and the industry's efforts in Japan and the EU. Furthermore, both sides adopted cloud computing as an issue for the 19th Japan-EU ICT Dialogue (November 2012 in Tokyo). In this dialogue, the Government of Japan presented "Smartphone Privacy Initiative –innovation for a new era through proper handling of user information and enhanced literacy" (released in August 2012), and both sides also exchanged information and views on policy trends

concerning user information and privacy in ICT services, such as user information on smartphones and shared best practices.

#### Future outlook

- The Ministry of Economy, Trade and Industry plans to hold an APEC workshop regarding the General Data Protection Regulation of the European Parliament and of the Council, inviting the officials from the Directorate-General for Justice of the European Commission.
- The Special Commission about Personal Information Protection in the Consumer Commission has been discussing the problem of personal data protection, which does not exclude the possibility of the review of the Act, and the Special Commission submitted the Report to the Consumer Commission. The Consumer Commission expressed their recognition that the problems raised in the report are important, and need to be considered continuously. The government of Japan will take into consideration the discussion of the Consumer Commission when it formulates its policy on personal information protection.
- Furthermore, based on “Smart Cloud Strategy,” the Government of Japan will continue its efforts to promote using the applications which utilize the cloud computing environment. In addition, the Government of Japan will produce a certain result in "Study Group on use and flow of personal data" by around July 2013.
- In “IT integration forum personal data WG”, it will be completed around March, 2012 about how to take the consent in the collection stage of personal data, and the state of confidential relation construction.
- Moreover, Japan and EU agreed at the Japan-EU ICT Dialogue in November 2012 that both sides will continue to exchange information for promoting cloud computing services.

## 8. ITA expansion (WP-C/#08/EJ to EJ)

### BRT Recommendation

The BRT recommends that both Authorities ensure that the current ITA is reviewed at the earliest opportunity and that additional electronic goods be granted duty-free status in addition to those that already have that status. The broadest possible expansion (including large portions of Chapters 84, 85 and 90) of the scope is needed so that current and future innovative technological developments should not cause product classification uncertainties.

- (1) The EU should complete its implementation of the WTO panel in the ITA dispute without further delay to avoid new convergence technology of ITA products being reclassified as dutiable.
- (2) The geographical coverage of the ITA should be expanded by encouraging more countries to join the ITA. Membership should be promoted as a means of boosting efficiency and productivity, improving the investment climate, helping bridge the digital divide and enabling the move to a more energy-efficient and climate-friendly society.
- (3) Effective mechanisms (such as fora for industry to explain state of the art technology to government) are needed to ensure the ITA is kept up to date and reflects technological developments.

### < Background >

By extending duty-free status based on the ITA, Japan and Europe will benefit from the development of a major industrial sector that is a driver of productivity, innovation, job creation, improved competitiveness and service quality in virtually all other sectors and in public services.

An ITA expansion would boost trade in the whole electronics sector, remove uncertainties relating to product classification and would ensure technological developments in the sector are more likely to be reflected as newly-developed products are more likely to fall in these chapters. Many non-participants still levy high duties on, and impose many NTBs against, imports of IT products. The removal and prevention of NTBs is of the utmost importance to the Japanese and European electronics industries. Positive developments through the extension of product scope and additional participants in the ITA would be compromised if NTBs were not properly addressed. NTBs undermine level playing fields in current and future ITA states. NTBs often increase after the abolition of duties and taxes.

APEC leaders agreed in the 19th APEC Economic Leaders' Meeting on 12-13 November 2011 in Honolulu, Hawaii, USA that APEC would play a leadership role in launching negotiations to expand the product coverage and membership of the ITA, in order to build on the contribution this Agreement has made to promoting trade and investment and driving innovation in APEC economies.

#### Action taken so far

Regarding the ITA expansion, at the ITA 15<sup>th</sup> anniversary symposium in May 2012, the global business community sent ITA members a clear and strong message of the need of the expansion of the ITA product coverage. At the formal meeting of the ITA committee held in the day right after the symposium, many members supported the launch of the negotiations to expand the ITA product coverage proposed by Japan and other major members. Since then, technical meetings have been held once a month by the interested members with a growing number of participants.

Regarding the EU implementation of the WTO panel reports, the Government of Japan (GOJ) requested, jointly with the United States and Chinese Taipei, to establish a panel pursuant to the WTO dispute settlement procedures regarding the EU's tariff treatment of multifunctional digital machines, flat panel display devices, and set-top boxes. The panel reports, accepting the claims made by co-complainants, were adopted by the Dispute Settlement Body in September 2010, and the EU agreed to implement measures for complying with the panel's recommendations by the end of June, 2011. However, the EU continues to impose tariffs on several products. The GOJ has been closely monitoring whether appropriate tariff treatment is accorded to the IT products in the EU.

#### Future outlook

Members will hold technical meetings as frequently as possible, in order to achieve an early agreement in the first half of 2013. In addition, members will also call on non-ITA members to join the ITA.

The GOJ will continue to request the EU to provide appropriate tariff treatment pursuant to the WTO panel's recommendations with respect to flat panel displays. The GOJ will communicate with EU Member States to ensure that the tariff treatment of IT products be implemented appropriately on various occasions including the ITA Committee of the WTO.

## 9. Harmonization between the EU and Japan for M2M communication and ITS (WP-C/#10/EJ to EJ)

### BRT Recommendation

Both Authorities should cooperate and lead the international harmonisation of M2M (Machine-to-Machine) communication and ITS (Intelligence Transport Systems) including standardization for technical specifications.

### <Background>

The world is already highly connected and it is about to get even more so: today, there are about six billion mobile subscriptions worldwide. As devices of all kinds become connected, there will be more mobile subscriptions than human population on the planet. It is expected that the number of connected devices increases with a factor of 10 over the coming decade.

Solutions for connected devices have been available for many years, but now we are entering a new phase of rapid growth in M2M services and consumer-device connectivity. Cost of connected devices is decreasing and value of connectivity is rising for individuals, businesses and society in general.

M2M connectivity offers an increasingly attractive way of adding value, improving productivity and reducing cost from a wide range of industrial and business processes, such as in the areas of Smart City, Smart Grid, e-Health and so forth. ITS stands for Intelligent Transport Systems and is the integration of information and communications technologies (ICT) with transport infrastructure, vehicles and users.

The overall purpose of ITS is to improve safety & security, increase efficiency and reduce environmental impact of the transport systems. Mobile network technologies are major enablers for critical ITS applications, building on an attractive economy of scale and speed of deployment.

### Action taken so far

MIC has started the project of “The development and experiment of communication standardizations in the era of Internet of Things” from 2012, aiming to establish optimal control technologies and standardize communication standards of machine-to-machine (M2M) communication.

Regarding ITS, MIC and Europe are cooperating and leading standardization activities such as the expansion of the frequency for 79GHz automotive radar.

### Future outlook

MIC will continue to develop and examine optimal control technologies and standardize communication standards of machine-to-machine (M2M) communication in the project of “The development and experiment of communication standardizations in the era of Internet of Things.”

Regarding ITS, MIC and Europe will continue to promote standardization activities such as the

expansion of the frequency for 79GHz automotive radar for the decision at WRC-15 which will be held in 2015.

## 10. Enhanced Cooperation between the EU and Japan on 21<sup>st</sup> Century societal challenges (WP-C/#13/EJ to EJ)

### (1) Support for flagship demo projects

#### BRT Recommendation

The BRT recommends that both sides' Authorities support flagship demo projects and innovative solutions to common societal challenges through deregulation, easing of investment, notably for SMEs, and inviting expertise from EU and Japanese industry.

#### Action taken so far

“Emergency Economic Measures for the Revitalization of the Japanese Economy” adopted at the Cabinet meeting in January 2013 stated as follows: (The English summary of the Measures is available through [http://www5.cao.go.jp/keizai1/2013/130111\\_emergency\\_economic\\_measures.pdf](http://www5.cao.go.jp/keizai1/2013/130111_emergency_economic_measures.pdf))

#### Implementation and realization of the strategy for growth

- Aiming to build a nation imbued with the concepts of “the most business friendly country in the world”, “a country where the potential of individuals is fully realized and employment and income grow”, and “Hybrid-Economy” driven by the twin engines for growth that consist of “Trade oriented country” and “Industrial investment oriented country”
- Encouraging business investment and innovation, facilitating the expansion of Japanese businesses in overseas markets, developing new markets through these measures and increasing jobs, strengthening human capital development and increasing jobs for the younger generation, and developing an environment where those who have failed can challenge again
- Developing the systems for implementing bold regulatory and institutional reform in the areas that have a potential of high growth  
(Excerpted from Provisional Translation of the Emergency Economic Measures for the Revitalization of the Japanese Economy (P2-3))

#### Future outlook

The Government of Japan is moving toward realization of Emergency Economic measures for the Revitalization of the Japanese Economy.

## (2) Enhancement of joint R&D projects between the EU and Japan

### BRT Recommendation

The BRT recommends further enhancement of joint R&D projects between the EU and Japan. Work towards international standardization should gain particular attention for such projects.

### Action taken so far

Through discussions at the First Japan - EU Joint Committee on Scientific and Technological Cooperation in Tokyo, June 2011 and the thematic consultations in various fields, Japan and the European Commission started the joint calls in the fields of “Development of New Materials for the Substitution of Critical Metals” in July, 2012, “ICT” in October, 2012.

Japan also participates in CONCERT-Japan, an ERA-NET initiative under the EU Seventh Framework Programme for Research and Technology Development (FP7), which aims to promote an effective and coordinated science and technology cooperation between Japan and European countries. As a part of the project, a pilot joint call was launched last September in the two fields of “Resilience against Disasters” and “Efficient Energy Storage and Distribution” in coordination with fourteen funding agencies from eleven European countries.

### Future outlook

The GOJ seeks the possibility of wider cooperation, with consideration on international standardization including the cases which could be commercialized in the future, by following up progress of the joint research which has been launched after the entry into force of the Agreement between the GOJ and the European Community on Cooperation in Science and Technology.

The GOJ and the EU are in the process of scheduling the Second Joint Committee on Scientific and Technological Cooperation during the early part of 2013.



### (3) Strategic budget allocation to innovation investment

#### BRT Recommendation

The EU, Member-States and Japan should continuously allocate strategic budgets to innovation investment particularly on education in science, technology, engineering and mathematics fields, and on developing competent human resources in S&T, as well as to R&D Infrastructures in national laboratories and universities. Strong ties with business should leverage this investment.

#### Action taken so far

The GOJ positions and promotes STI policy as the foundation of the national strategy. The Council for Science and Technology Policy (CSTP), which is under the Cabinet Office, endorsed the “Policies for the Allocation of Resources including the S&T Budget -FY2013-” in July 2012, and indicated to promote “Response to the Priority Issues Facing Japan” and “Enhancement of Basic Research and Human Resource Development.” The latter, constituting the foundation for the national innovation, is inseparable from the former. The CSTP formulates Action Plan (AP) which shows the policy direction for prioritization of S&T budget responding to the priority issues.

#### Future outlook

The GOJ will implement initiatives to optimize the budgets allocation required for promoting STI policy by utilizing various tools like AP.

#### (4) Tax credits for R&D

##### BRT Recommendation

Tax credits for R&D should be expanded to encourage private sector investment in R&D.

##### Action taken so far

The Government of Japan (GOJ) extended special treatment of R&D tax credit(selective system “increased type” or “high-level type”), which otherwise was expired at the end of FY2011, for two years in FY2012 Tax Reform.

##### Future outlook

The GOJ decided the following two issues in the FY2013 Tax Reform (Cabinet Decision on January 29, 2013).

- (1) Raise the maximum deductible amount of tax credit based on total R&D spending from 20% to 30% of a corporation’s corporate income tax liability
- (2) Add certain joint research to the scope of special experiments and research expenditures from April 1<sup>st</sup> in FY2013 Tax Reform.

## 11. Business cooperation between EU and Japanese clusters (WP-C/#14/EJ to EJ)

### BRT Recommendation

Strengthen business cooperation between EU and Japanese clusters. Specifically:

(1) The Authorities of the EU and Japan should support the EU-Japan Centre for Industrial Cooperation and the European Cluster Collaboration Platform to further advance their cluster cooperation agenda.

(2) A more strategic use of clusters should be made to support SME internationalization and global competitiveness, especially in emerging industries where cluster cooperation would have a strong impact.

(3) The Authorities of the EU and Japan should intensify cooperation between EU and Japanese clusters by giving a stronger focus to concrete actions. In particular, both authorities should support and facilitate the organization of matchmaking events between EU and Japanese clusters in strategic areas of mutual interest.

### < Background >

Clusters create a fertile business environment at local level fostering innovation, increasing productivity, enhancing cooperation between academia and industry, and facilitating internationalisation of SMEs. Japan and EU countries have many clusters, some of them world-class, innovation-driven and competitive in global markets, and open to international cooperation. There is an increasing business interest and scope from both sides to strengthen cooperation between clusters.

To facilitate and have a more institutionalised and sustainable approach, a MoU has been signed between the European Cluster Collaboration Platform and the EU-Japan Centre located in Tokyo and Brussels. Thanks to this MoU, Japanese clusters will be able to use this platform to identify partners in EU countries (and vice versa), explore opportunities with them, develop visiting schemes for their companies and start developing joint R&I projects.

### Action taken so far

The Industrial Cluster Policy has strengthened the global competitiveness of Japanese industries and invigorated Japan's local economies by businesses, universities, and other institutions, in regions throughout Japan, forming wide-area networks through partnerships between businesses in the same industry, and across industrial sectors from fiscal 2001. Those networks, through synergetic sharing of participant's intellectual and other resources, will then reach the state in which they have generated new industries and businesses, mainly in their regions.

Those networking activities are currently carried out as regional clusters mainly led by private organizations and local governments.

In the open session of the "Europe green material cluster missions" held in Tokyo in November, 2012

sponsored by the European Commission Enterprise and Industry Directorate General and the EU-Japan Centre for Industrial Cooperation, etc., while the importance of cooperation with the cluster organization of overseas, such as Japan- EU, is shared. In subsequent working-level exchange of opinions, the cluster cooperation in the business-level between Japan and EU was confirmed the importance of performing continuously, in the field of renewable energy, life science, and functional foods especially.

#### Future outlook

The business-level international exchange and cooperation is expected to further progress through cooperation between the clusters of Japan and EU member states.

## 12. Government-Led Industrial Cooperation in Aeronautics (WP-C/#15/EJ to EJ)

### BRT Recommendation

The Authorities of Japan and the EU should significantly upgrade the scale of EU-Japan industrial cooperation in aeronautics, stimulated by government funding.

#### <Background>

Europe's aeronautics industry has long been a major supplier to the world market. Japan also has many advanced technologies. Both are now challenged by new entrants. In this context, joint technology and project development are necessary for both sides' companies to maintain technological leadership and competitiveness. It is also a necessity for governments faced with severe budgetary constraints. Europe-Japan industrial cooperation already exists in helicopters and aeroengines but the potential is much greater. More government-led cooperation between Japanese and EU industries would result in many gains for both sides. In the civil airliner area, EU-Japan industrial cooperation has stagnated since the early 2000s, when 21 Japanese suppliers joined the A380 programme. Japan lost many opportunities of working with European industry in aerostructures. The situation is better for Japanese participation in engine programmes and as suppliers of carbon fibre materials. The aerospace industries of other countries have evolved significantly in recent years, both in skills and capacity, and price competitiveness has become a key decision criterion. The strength of both the Euro and the Yen against the US\$ plays against cooperation between Europe and Japan. A possible strategy for Japan is to develop supply chains in the region in order to enhance the prospects for competitiveness and further cooperation with Europe.

### Action taken so far

1. In June 2005 the Society of Japanese Aerospace Companies (SJAC) and the French Aerospace Industries Association (GIFAS) agreed to conduct joint research on the development of a supersonic passenger aircraft (supersonic transport: SST). In July 2008, both agreed to extend the project period for another three years, and in June 2011, agreed to extend it for another three years. For the Japanese side, the Japan Aircraft Development Corporation (JADC), the Engineering Research Association for Supersonic Transport Propulsion Systems (ESPR), and the Japan Aerospace Exploration Agency (JAXA) participated in the project, while EADS, Snecma, and ONERA, the French national aerospace research centre, representing the French side are involved.
2. In July 2006 the Research Center of Advanced Metals and Composites (RIMCOF), which plays a central role in the Ministry of Economy, Trade and Industry (METI)'s development of basic materials-related technology, and Airbus agreed to conduct joint research on structural health monitoring (SHM) of aircraft. The project lasted until 2012. 【Currently, they are working on extension of the project term for another 3 years.
3. In December 2008, with a view to promoting the application of Japanese innovative technology in aircraft, METI organized a workshop on innovative technology of aircraft, in collaboration with Airbus and companies with innovative technology.

4. In November 2009, a private-public workshop was organized to promote research and technical cooperation between Japan and the Europe in the aerospace industry. In December 2010, Ministry of Economy, Trade and Industry (METI) and the European Commission (EC) held the second workshop with the participation of the Society of Japanese Aerospace companies and Aerospace and Defense industries Association of Europe. In June 2012, METI and the EC have publicly solicited ideas for joint research projects on aeronautics and air transport and adopted three respective projects on anti-icing system, surface heat exchanger for aero-engines, and high speed aircraft, which have been implemented in the beginning of 2013.
5. In July 2011, the Society of Japanese Aerospace Companies (SJAC) and Aerospace and Defense Industries Association of Europe (ASD) launched a project called SUNJET (Sustainable Network for Japan Europe Aerospace Research and Technology Cooperation) with a view to defining set possible areas of mid- and long-term cooperation between Japan and the Europe in the areas of airframe, engine and systems and equipment . After three rounds of workshops, in October 2012, a roadmap for the future cooperation was adopted.
6. Japan Aero Engines Corporation (JAEC), Germany's MTU, and other firms established a consortium named International Aero Engines in order to jointly develop and manufacture the V2500 aircraft engine. Japanese companies have also been involved in Rolls Royce's Trent 1000 and Trent XWB aircraft engine project, and have been jointly developing and manufacturing with Rolls Royce.
7. 21 Japanese companies were involved in the development of the Airbus's super jumbo jetA380, in the areas of cargo door, vertical tail and carbon fiber.
8. The Guidelines for Overseas Transfer of Defense Equipment etc. were issued in December 2011 as a statement by the Chief Cabinet Secretary.

#### Future outlook

It is encouraging that steady progress has been made in the cooperation between Japanese and European companies in recent years. We expect further development of such cooperation. The Government of Japan (GOJ) will continue its support for the collaboration between the Japanese aircraft industry and those of other countries, including the Europe. The GOJ will also consider possible cooperation in accordance with the Guidelines for Overseas Transfer of Defense Equipment etc.

### 13. Environmental Issues in Aeronautics Technology(WP-C/#16/EJ to EJ)

#### BRT Recommendation

The Authorities of Japan and Europe should establish broad bilateral cooperation on environmental issues.

#### <Background>

Europe and Japan support mostly separate research programmes on environmental issues, from noise to emissions. One joint effort is a British-Japanese cooperation on the Trent family of wide-body engines. Japanese involvement is slowly growing as new models are being added. Another effort is part of a small French-Japanese programme on high speed aeronautics technologies. We believe that the eco-technology at all aircraft speeds is one of the fields where further cooperation between Europe and Japan could yield significant cooperation and business opportunities.

#### Action taken so far

1. In June 2005 the Society of Japanese Aerospace Companies (SJAC) and GIFAS, the French aerospace industries association, agreed to conduct joint research on the development of a supersonic passenger aircraft (supersonic transport: SST). Later, in July 2008, they agreed to extend the project for another three years. From the Japanese side, the Japan Aircraft Development Corporation (JADC), the Engineering Research Association for Supersonic Transport Propulsion Systems (ESPR), and the Japan Aerospace Exploration Agency (JAXA) are participating in the project, while on the French side, EADS, Snecma, and ONERA, the French national aerospace research centre, are involved. The collaboration has been continued in the area of advanced composite manufacturing materials, jet noise reduction technologies and etc. which are indispensable for the future realization of an SST.
2. Since June 2012, METI and the EC have made a coordinated call in the field of aeronautics and air transport. The topics adopted include, environmentally-enhancing surface heat exchanger and zero-emission targeted high speed aircraft. Besides, since January 2013, METI and the EC have made a coordinated call, together with other country governments, aiming at flight testing of (a) multidisciplinary optimized model vehicle(s) in the hypersonic range relevant to an environmentally and economically sustainable civil aircraft.
3. Japanese companies have been involved in Rolls Royce's Trent 1000 aircraft engine project, working on development jointly with Rolls Royce.

#### Future outlook

With respect to efforts to develop environmentally-enhancing aircraft technologies, the cooperation between the Japanese aircraft industry and those of other countries is vital from the viewpoint of improvement of Japanese companies' technological capability and competitiveness. The Government of Japan intends to continue assisting in forging ties between the Japanese aircraft industry and those of other countries, including the EU.

#### 14. Cooperation in aircraft certification (WP-C/#17/EJ to EJ, WP-A/#07/E to J )

##### BRT Recommendation

Cooperation between Japanese and European aircraft certification authorities should be upgraded. Specifically, EU-Japan cooperation should be upgraded at the level of a full bilateral agreement. The use of English for all relevant documents should be permitted.

##### <Background>

There is a bilateral agreement between US and Japanese civil aviation authorities that facilitates the mutual acceptance of the other party's certification basis, while there is only a working arrangement between Europe (EASA) and Japan (JCAB) that proves extremely difficult to work with. Validation by JCAB of European Type certified aircraft is a very lengthy process. In particular, validation of EASA-certified new optional equipments for helicopters whose Type Certificates are already validated by JCAB should be almost automatic, but instead the Japanese authority requires a review of all the technical documentation before approval. This is often the cause of delivery delays of the products to Japan and may at times preclude European manufacturers from fairly competing in public tenders, due to stringent delivery requirements. Moreover, Japan is probably the only country in the world where the Rotorcraft Flight Manuals must be translated into the local language and approved by the local authority, again representing an obstacle to helicopter imports.

Recently, Japanese civil aviation certification resources have been drained by a local development project (i.e. MRJ) at the expense of imported products leading to significant delays (and costs) in airworthiness clearance for European products.

##### Action taken so far

In order to enhance cooperation between Japan and the EU for a high level of civil aviation safety, Ministry of Land, Infrastructure, Transport and Tourism and the European Commission agreed to launch preliminary discussions toward the conclusion of Bilateral Aviation Safety Agreement (BASA) at the Japan-EU Transport Dialogue held in July of 2011. In accordance with the agreement, the JCAB and European Commission are coordinating toward concluding BASA.

Regarding the Type Certificate of aircraft, the international standards of International Civil Aviation Organization (ICAO) require that importing States conduct technical evaluation on the basis of satisfactory evidence, even though the exporting States issue type certificate. Based on the international standards, JCAB validates Type Certificate of all importing aircraft equally, and the validation on Type Certificate of European aircraft, including optional equipments, is conducted in accordance with the Working Arrangement between civil aviation authorities of Japan and the EU.

Pilots need to understand the flight manuals, which include the operational limitation, the emergency procedures, etc., easily and surely at any situations in order to secure the safe operation of aircraft. The users of flight manuals are not specified because flight manuals belong to aircraft, and flight manuals should be understood properly even by those who are not secured English proficiency.



Therefore, JCAB basically requires and approves the Japanese flight manuals. JCAB have heard from some aircraft manufactures that flight manuals are prepared in the language other than English in some States.

JCAB's type certification activities for Japanese manufacturing aircraft, including MRJ, have been carried out by the special organization, which is separate from the organization for the inspection of importing aircraft. The organizations for the importing aircraft have been strengthened.

#### Future outlook

JCAB will continue to work with EU for the early conclusion of BASA.

15. Cooperation on navigation regulations for helicopters (WP-C/#18/EJ to EJ, WP-A/#07/E to J)

**BRT Recommendation**

(WP-A /#07/E to J)

Establish an increased level and better cooperation between Europe and Japan on the development of low altitude IFR routes and satellite based navigation regulations for helicopters.

< Background >

The US, Europe and Japan are working on developing their own regulations and infrastructure without an adequate level of exchange of information and standardisation. European and Japanese territories have more similarities than each has with the US, so that Europe and Japan should work more closely and with a shared approach. Many European helicopters are already equipped with the hardware to interface with ground based infrastructure already established to allow low altitude IFR routes and satellite based navigation, but that may prove useless if there is no cross recognition of standards and regulations (software) between the countries.

(WP-C/#18/EJ to EJ)

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**Action taken so far**

The establishment of low altitude IFR routes for small aircrafts including helicopters is now being considered, taking into account the needs of an operator in the committee by participants of industry, academia and government based on long-term vision on future Air Traffic Systems (CARATS) in Japan.

**Future outlook**

SESAR, the new European air traffic management systems modernisation programme and CARATS have concluded the agreement and established a framework for the technical cooperation toward this modernisation between the EU and Japan. Information exchange between Japan and Europe regarding to setting of low altitude ATS routes would be consulted to the EU through this framework.

## 16. Civil Purpose Satellite Technology (WP-C/#20/EJ to EJ)

### BRT Recommendation

In the civil satellite technology field, Japanese space Authorities (at Cabinet level) and European space Authorities (EU Commission, European Space Agency, and Europe's national space agencies) should establish a common mechanism for a formal and permanent dialogue with the purpose of identifying further mutually beneficial subjects of cooperation. Of particular interest to both the EU and Japanese industries are advanced broadband and mobile communications services that would be applicable, among other cases, to the rescue of populations hit by a natural disaster.

### <Background>

Europe and Japan have many complementarities in satellite technology and similar needs in terms of space telecommunications, broadcasting and observation. Note that discussions and cooperation on advanced technologies are also useful to promote common EU-Japan standards and thus benefit both sides' industries.

### Action taken so far

N.A.

### Future outlook

The Government of Japan will consult with the appropriate European space Authorities if there is a request from the EU Authority.

## 17. Mutual Backup of Government Satellite Launches (WP-C/#21/EJ to EJ)

### BRT Recommendation

Japanese and EU Authorities should bring about a mutual backup cooperation scheme of all government launches using their respective satellite launcher fleets.

### <Background>

Europe's satellite launcher Ariane 5 and Japan's H-IIA are used in an arrangement to back up each other's satellite launches on a commercial basis. This reduces the risk of long launch delays due to launcher technical problems. Years of discussions between Japan's MEXT and the European Space Agency towards a similar back-up arrangement for government launch missions have not produced results.

### Action taken so far

N.A.

### Future outlook

The Government of Japan will consult if there is a request from the EU Authority.

## 18. Cooperation on Satellite Navigation Systems (WP-C/#22/EJ to EJ)

### BRT Recommendation

EU and Japan Authorities should establish a close cooperation between Galileo and the Quasi-Zenith Satellite System. This should include frequency management, handset technology (receiver chips) development, and cooperation in GNSS meetings to set up service standards. Furthermore, the EU and Japan should develop cooperation on GNSS downstream applications.

### <Background>

The EU's Galileo and Japan's Quasi-Zenith Satellite System will soon become reality. Augmentation and various commercial services are among many mutually beneficial applications that require extensive mutual information between EU and Japanese Authorities and their encouragement and facilitation of industrial cooperation.

Cooperation in frequency management is required because unlike GPS, both Japan and Europe operate multiple frequencies for different services. Other important questions include anti-jamming technology development and receiver chip technology development (important for economies of scale).

### Action taken so far

In the Joint Press Statement at the 20th Japan-EU Summit in Brussels in May 2011, Japan and the EU shared the view that Japan and the EU will explore the possibility of establishing a cooperation framework on satellite navigation at governmental level. Currently the cooperation framework is under consideration.

### Future outlook

The GOJ will continue to explore the possibility of establishing a cooperation framework at government level. In the meantime, frequency coordination between Quasi-Zenith Satellite System and GALILEO would be the main theme.

## 19. Cooperation on Active Space Debris Removal (WP-C/#23/EJ toEJ)

### BRT Recommendation

EU and Japan Authorities should lead a global effort to remove space debris from low and geostationary Earth orbits. Near-term bilateral cooperation should include defining debris removal standards (or code) and developing debris removal technologies.

### <Background>

Space debris are a serious threat to today's commercial utilisation of space. Because of their peaceful policies, Japan and the EU are best positioned to define debris removal standards (or code) then lead and help police a global effort to remove debris from low and geostationary Earth orbits. Japan's and Europe's Space Situational Awareness programmes and the EU Commission's draft Code of Conduct for Outer Space Activities can serve as a basis and starting point towards that effort.

### Action taken so far

In January 2012, Former Minister for Foreign Affairs, Koichiro Genba, and Former Minister for Space Policy, Motohisa Furukawa welcomed EU's initiative to develop "International Code of Conduct for Outer Space Activities" and expressed Japan's preparedness to participate actively in the international discussions on this matter. In order to make the Code truly international, Japan has been participating actively in the discussions, such as the multilateral meeting in June, and stressed the importance of protecting space environment and encouraging participation of Asian countries in the international discussion for developing a Code.

On a technology front, the Japan Aerospace Exploration Agency (JAXA) is conducting comprehensive research on space debris in four areas: observation, modeling, protection, and mitigation. Japan has the optical telescopes and the radar system for observing space debris.

### Future outlook

In order to ensure stable and sustainable space environment, Japan continues to participate in and contribute actively to the creation of international norms. In order to ensure secure and stable space development and utilization, Japan will conduct studies on system of Space Situational Awareness (SSA) necessary for protecting the International Space Station (ISS), satellites and astronauts against debris. Japan will steadily conduct development of debris removal technologies required in the world, facilitating international collaboration and leveraging Japan's own strength.

## 20. Exchange and Protection of Classified Information (WP-C/#25/EJ to EJ)

### BRT Recommendation

Japan and European countries should make official agreements for government and industry to exchange and protect classified information pertaining to promotion of products and to joint development.

### <Background>

European and Japanese defence industries have many complementarities and could, if they were allowed to fully cooperate, jointly develop high performance and cost-efficient products and technologies that are necessary to the forces of both sides. This is made almost impossible as European and Japanese companies cannot directly exchange classified information on the products or technologies

European Governments and defence companies provide classified and/or commercially sensitive information during product promotion and development/production. The same may also occur when a relaxation to the Three Principles on Arms Exports is in place which would enable the Japanese Government and Japanese defence companies to co-develop with European industries and/or to promote products to Europe. Such classified/sensitive information must be adequately protected.

A positive step was made in October 2011 when a bilateral agreement covering the exchange and protection of classified information was signed by the French and Japanese authorities

Action taken so far As for the classified information under the control of Japan Ministry of Defense, regulations for transmission and commission have been established to outside which are based upon directions stipulated by Defense Minister, etc.

In addition, the Agreement between the Government of Japan and the Government of French Republic on the security of information was concluded in October 2011. Both countries have agreed to ensure the reciprocal protection of classified information exchanged between Japanese and French governments, including Japan Ministry of Defense. The Agreement provides the procedures for protecting the classified information appropriately, subject to both countries' national laws and regulations

### Future outlook

N.A.

## 21. Relaxation of the Three Principles on Arms Exports (WP-C/#26/EJ to J)

### BRT Recommendation

The announcement of a relaxation to the Three Principles on Arms Exports is warmly welcomed.

The announcement on 27th December 2011 should be underlined by a set of clear guidelines, rather than one off exceptions for specific purposes. These guidelines should be gradually put in place during 2012.

The guidelines should provide Europe with equal opportunities to those provided to the US.

### <Background>

An announcement was made by the Japanese Government Cabinet Office on 27<sup>th</sup> December 2011 regarding Guidelines for Overseas Transfer of Defense Equipment etc. – i.e. a relaxation to the 3 Three Principles on Arms Exports.

### Action taken so far

The Government of Japan (GOJ) released “Statement by the Chief Cabinet Secretary on Guidelines for Overseas Transfer of Defense Equipment etc” on December 27, 2011. This guideline enables overseas transfer of defense equipment etc. on cases related to peace contribution and international cooperation and international joint development and production of defense equipment etc. contributing to Japan’s security on the premise that strict control is in place.

In order to go forward concrete international joint development and production, it is needed to set a frame work between the GOJ and a country concerned to ensure strict control. The detail of the frame work will be coordinated between the GOJ and each country concerned.

### Future outlook

The GOJ will deal with each individual case in accordance with the above guidelines.



## 22. Facilitation of Re-export of Defense Equipment Imported for Demonstration Purposes (WP-C/#27/EJ to J)

### BRT Recommendation

Japanese Authorities should implement simple procedures to facilitate re-export of defence equipment imported for the purposes of demonstrations at forums such as trade fairs and exhibitions.

### <Background>

Defence export regulations make it difficult for foreign firms to re-export defence equipment they import for the purposes of demonstrations at trade fairs, exhibitions and other forums. This severely constrains their ability to market their products.

Special re-export arrangements for defence equipment imported into Japan for these purposes would give Japanese procurement agencies a better understanding of the full range of options available.

### Action taken so far

The Three Principles on Arms Exports and their related policy guidelines are based on Japan's basic philosophy to avoid the exacerbation of international conflicts as a peace-loving nation. The Government of Japan (GOJ) firmly maintains this basic philosophy.

Based on the Foreign Exchange and Foreign Trade Act and the Export Trade Control Order, an export license is necessary to re-export defense equipment imported for the purposes of demonstrations.

### Future outlook

As the current view, an export license is still necessary to re-export defense equipment imported for the purposes of demonstrations based on the Foreign Exchange and Foreign Trade Act and the Export Trade Control Order. The GOJ does not apply special procedure to foreign entities.

## **Working Party D: Financial Services, Accounting and Tax Issues**

### 1. Progress in the financial market reform since the financial crisis (WP-D/#01/EJ to EJ)

#### BRT Recommendation

- Regulation on the financial sector should be implemented looking ahead the broader economic implication
- An excessive ‘ring-fencing’ in each jurisdiction and duplication of regulations have to be avoided with effective supervision and international coordination
- Consider local specificities of each country and region when discussing regulation in a global context

< Background >

#### Overview

There is a need to revitalise global economic growth and restore confidence. Regulation should be designed and implemented looking ahead the broader economic implication; otherwise the financial sector may be safer but not able to fulfil its role to support economic recovery.

Regardless of how superior regulatory architecture is built up, the key to develop a resilient and efficient financial system will eventually rest upon effective supervision and coordination.

In this respect, the BRT is strongly concerned if excessive ring-fencing policies were pursued in each jurisdiction in a different manner. To address the so-called ‘too-big-to-fail’ issue properly, the BRT appreciates the ongoing, serious efforts by the authorities around the world to develop an effective cross-border resolution regime and prepare recovery and resolution plans. This requires very sensitive and highly intense international coordination and cooperation among the regulators. However, banks are now struggling with the requirement to build up much stronger liquidity buffers than stipulated under Basel III from various host country requirements for local ‘ring-fencing’. Without a more carefully coordinated approach, some host countries might opt for ring-fencing policies, increasing demands on banks to build up additional liquidity buffers, resulting in more deleveraging and pose negative effects to the real economy, including in those host countries.

To minimise the risk of these regrettable consequences occurring, more focus should be placed on encouraging consolidated banking supervision by home country regulators, which is one of the most efficient international regulatory frameworks that authorities around the world have developed to date.

#### Taking into consideration local specificities of each country and region

Regulation needs to fully take into account circumstances that are specific to each country and region, the variety of financial players, and respect their business models and their time horizons. The different economics of financial activities and market mechanisms should be appropriately reflected in the new regulatory regimes.

According to “Basel III”, investments in the capital instruments of banking, financial and insurance entities would be deducted. However, for countries where reciprocal cross holdings in the capital between financial institutions are prevalent, sensitive handling such as giving an adequate transition period would be necessary.

Regulatory capital instruments such as contingent capital or debt instruments with bail-in clauses designed by financial regulatory authorities need to be introduced with sufficient consideration for market capacity.

Current policy discussions for tightening regulation and oversight over shadow banking system, led by the FSB, needs to carefully consider if any unintended consequences or risks to regulatory arbitrage were induced. Apart from wider systemic risk regulatory perspective, the authorities should give due consideration that any additional rules affecting existing market mechanisms or well-established market practices may hinder legitimate role of financial intermediaries and disturb other bona fide business activities.

For completing successful global financial sector reform, the BRT believes that internationally consistent regulations should be built and implemented with level-playing field among players and markets through multilateral discussions on a global basis. Among other things, the impact on the revitalisation of global economy growth and cumulative impacts due to each regulatory reform when they are concurrently being implemented should be taken into account fully.

#### Action taken so far

Japan has contributed to international discussions with a view that it is important to take a balanced approach by simultaneously strengthening the financial system and giving due consideration to possible effects on the real economy. Such view is reflected in international agreements, including Basel III, and Japan has propelled their domestic implementation. With respect to Basel III implementation, Japan amended the administrative notice based on the Banking Act in March 2012 to put in place national regulations consistent with Basel III. Moreover, in view of international discussions at the FSB and other forums, Japan is moving ahead with the development of recovery and resolution plans for large, complex, and internationally active financial institutions in cooperation with the relevant authorities.

#### Future outlook

Japan is striving to prevent a recurrence of financial crisis and further ensure stability and soundness in the financial system in cooperation with the relevant authorities based on international agreements, including the ones reached at the G20 Finance Ministers and Central Bank Governors’ Meeting in 4-5 November 2012. Japan will continue to actively take part in international discussions, for example, to establish a framework on oversight and regulation on shadow banking which is sufficient to deal with the risks and characteristics of shadow banking in each jurisdiction while preventing regulatory arbitrage.

## 2. Tax Issues in Japan (WP-D/#10/EJ to J)

### (1) 2012 Tax reform

#### BRT Recommendation

Review 2012 tax reform limiting deductible interest to 50% of taxable income to:

- exclude interest income subject to Japanese withholding tax
- increase threshold to 300 million yen
- introduce unlimited carry-forward of non-deductible interest and of unused amounts
- limit pick-up of interest exceeding average world-wide group interest burden

#### < Background >

The new rule limiting interest deduction to 50% of taxable income (after adjustments for interest and depreciation) under the proposed Tax Reform 2012 will curb foreign investment into Japan as it will cause double taxation of interest income in both the foreign investor's home country as well as in Japan. It will also create a burdensome need for local refinance in Japan in turbulent financial markets.

#### Action taken so far

For the Japanese Government's overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

#### Future outlook

For the Japanese Government's overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

## (2) Transfer pricing

### BRT Recommendation

- Review transfer-price taxation based on international common models such as OECD model
- All cross-border transactions should be dealt with under transfer pricing legislation and not under domestic corporate tax rules relating to donations
- Consistency between transfer pricing methodology for audit assessment and methodology used in Advanced Pricing Agreement

### Action taken so far

(1) The GOJ makes it a practice to publicly release, on websites, not only the laws and regulations on the transfer pricing taxation, but the Administrative Guidelines on its interpretation and on its operations. Also, in order to increase predictability for taxpayers by further clarifying its operations, the National Tax Agency of Japan (NTA) has been updating the Administrative Guidelines with public consultations.

(2) The Administrative Guidelines prescribe that examinations and APA reviews are conducted with due reference to the OECD Transfer Pricing Guidelines (TPG), and the NTA has been making efforts to administer the transfer pricing taxation system based on such international rules.

For the Japanese Government's overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

### Future outlook

From the viewpoint of ensuring transparency and facilitation in transfer pricing administration, the NTA will continue to bring further clarifications to its application standards and administrative policies by updating the Administrative Guidelines with reference to the TPG.

For the Japanese Government's overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

### (3) Applications for tax rulings and tax law

#### BRT Recommendation

Tax authorities to accept and process applications for tax rulings and tax law to provide for right to request and obtain tax ruling.

#### Action taken so far

For the Japanese Government's overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

#### Future outlook

For the Japanese Government's overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

## **Working Party E: Energy, Environment and Sustainable Development**

### **1. Leadership role to establish world safety standards (WP-E/#05/EJ to EJ)**

#### **BRT Recommendation**

The EU and Japan should take a proactive, leading role in supporting the establishment of world safety standards for nuclear power plants through the IAEA and more generally promote international cooperation on nuclear energy.

#### **Action taken so far**

Japan sees it as its responsibility to share with the international community knowledge and lessons learned from the accident at TEPCO's Fukushima Daiichi Nuclear Power Station in March 2011, and has promoted discussion at international fora to strengthen nuclear safety worldwide. Japan organized the Fukushima Ministerial Conference on Nuclear Safety in Koriyama-city of Fukushima Prefecture in December 2012, in co-sponsorship with the IAEA, to share with the international community further knowledge and lessons learned from the accident, to further enhance transparency, and to discuss the progress of the international efforts aimed at strengthening nuclear safety.

Additionally, Japan has actively taken part in international efforts such as reviewing IAEA safety standards.

#### **Future outlook**

Japan will further promote discussion at international fora to continuously improve nuclear safety by providing the international community with the updated status of the accident in an accurate and expeditious manner, and sharing lessons learned with the international community. Additionally, Japan will actively take part in international efforts such as reviewing IAEA safety standards.

## 2. Nurturing skilled independent nuclear safety authority (WP-E/#06/EJ to EJ)

### BRT Recommendation

Japan and EU member countries should maintain a highly skilled nuclear safety authority in each country and ensure its independence.

### Action taken so far

The Government of Japan (GOJ) has been engaged in restructuring of agencies responsible for nuclear safety regulation with a view to recovering public trusts for the nuclear safety administration and improving its functions. The GOJ established the Nuclear Regulation Authority by separating the Nuclear and Industry Safety Agency (NISA) from the Ministry of Economy, Trade and Industry and integrating the tasks of other organizations including the Nuclear Safety Commission (NSC), from the viewpoints of “separating functions of nuclear regulation from promotion” and unification of the related nuclear safety tasks. In this way, the GOJ will ensure independency of the regulatory agency for nuclear safety, and enhance the effectiveness of the regulation through strengthening the legal regulation for safety and human resource development.

### Future outlook

The GOJ has been implementing effective nuclear safety regulation under an independent organization through establishing the Nuclear Regulation Authority in September 2012 and strengthen the safety regulation.



### 3. Cooperation on renewable energy development (WP-E/#07/EJ to EJ)

#### BRT Recommendation

Japan and the EU should cooperate on the development of renewable energies, such as wind and photovoltaic power generation, and on other low-carbon technologies such as carbon capture and sequestration (CSS).

#### Action taken so far

Japan and European countries such as France and Spain started the Smart Community demonstration projects utilizing renewable energy FY2011. New Energy and Industrial Technology Development Organization (NEDO) is implementing these projects in cooperation with French and Spanish governments.

In addition, Japanese and European institutions are cooperatively developing technologies of the concentrator photovoltaic cells based on the cooperation framework that was agreed between NEDO and European Commission (FP7) in May, 2011.

The Ministry of Economy, Trade and Industry (METI) started to launch design, construction and other processes for the necessary facilities (more than 100,000 tonnes of CO<sub>2</sub> will be captured per year) for the demonstration project of CCS at the Tomakomai site in FY2012.

#### Future outlook

The Smart Community demonstration projects in France and Spain will be continued until FY 2015.

Collaborative research of concentrator photovoltaic will be continued until FY 2014.

The Ministry of Economy, Trade and Industry (METI) will continue to design and construct of equipment necessary for the demonstration of CCS until FY2015.

#### 4. Promoting reciprocal access to R&D facilities (WP-E/#08/EJ to EJ)

##### BRT Recommendation

The EU and Japan should support joint R&D activities or mutual access to unique, capital intensive R&D facilities located in either the EU or Japan.

##### Action taken so far

Japan constructs advanced research facilities possessing incomparable capability in accordance with the "Act on the Promotion of Public Utilization of the Specific Advanced Large Research Facilities" (Law No. 78 of 1994) and facilitates shared use among researchers in various fields. Japan gives out the access information on these facilities for overseas users and promotes construction of a system which is open to foreign researchers' application.

In addition to regular calls for shared use of four facilities (SPring-8, SACLA, J-PARC and K Computer), consultation services for utilization of these facilities is also available at any time.

##### Future outlook

Toward the 2nd Joint Committee on Scientific and Technological Cooperation, which is in the process of scheduling during the early part of 2013, the GOJ will follow-up the discussion in the 1st Joint Committee, and seek the possibility of future cooperation by following up the progress of the joint researches which have been launched in 2012.

5. Sharing best practices for safety and regulation with emerging nuclear power countries (WP-E/#09/EJ to EJ)

#### BRT Recommendation

The EU and Japan should position nuclear power as an alternative energy and provide assistance to each other and to other countries, giving priority to sharing best practices in the fields of regulation and safety. The EU and Japan need to effectively support emerging nuclear power countries through a combination of bilateral, regional, and cooperative activities through international organisations.

#### Action taken so far

Japan has advanced bilateral cooperation, regional cooperation, and cooperative activities through international organizations to communicate the situation of the accident at TEPCO's Fukushima Daiichi Nuclear Power Station to emerging nuclear power countries, and share the lessons learned from the accident with them.

Concerning bilateral cooperation, Japan provided training programs for the capacity building of regulators and licensees of China and Vietnam through Japan Nuclear Energy Safety Organization (JNES). Japan has also communicated the status of the accident to the international community in an accurate and timely manner, and shared the lessons learned at the Northeast Asian Top Regulators Meeting on Nuclear Safety held in Seoul last November and other opportunities.

As for regional cooperation, Japan has actively taken part in the Asian Nuclear Safety Network (ANSN) of the IAEA for supporting to establish nuclear safety infrastructures in emerging nuclear power countries in Asia, and attended its General Conference held in September, 2012 and steering committee meeting held in November, 2012.

Japan organized the Fukushima Ministerial Conference on Nuclear Safety in Koriyama-city of Fukushima Prefecture in December, in co-sponsorship with the IAEA, where Japan shared with the international community further knowledge and lessons learned from the accident, further enhanced transparency, and discussed the progress of the international efforts aimed at strengthening nuclear safety.

#### Future outlook

Japan will continue to promote bilateral cooperation, regional cooperation, and cooperative activities through international organizations to communicate the situation of the accident at TEPCO's Fukushima Daiichi Nuclear Power Station to emerging nuclear power countries, and share the lessons learned from the accident with them.

6. Fostering international harmonization for EV safety and charging infrastructure (WP-E/#12/EJ to EJ)

#### BRT Recommendation

The EU and Japan should work together in UN-ECE WP 29 and others to develop internationally harmonized requirements for the safety and type approval of electrically charged vehicles and common standards for accessing the battery-charging infrastructure.

#### Action taken so far

In the World Forum for Harmonization of Vehicle Regulations (UN/ECE/WP29), the Informal Group on Electric Vehicle Safety (EVS) was set and has discussed to establish the Global Technical Standards on EVS under the initiative of U.S., EU and Japan. WP29, at its 158th session held in November 2012, agreed the terms of reference (TOR) of the Informal Group on EVS including the protection against electrical shock.

Standardization of charging infrastructure has been discussed in international discussion table such as IEC.

#### Future outlook

Based on the TOR of Informal Group on EVS agreed at the 158 session of WP29, U.S., EC and Japan will advance the consideration toward an establishment of a global technical regulation on EVS in cooperation with each other.

When we discuss standardization of charging infrastructure, we should develop them in order to ensure drivers' benefit and convenience. Infrastructure developments should not be exclusive to the existing vehicles and chargers.

## 7. Cooperation on pre-commercial development of batteries (WP-E/#13/EJ to EJ)

### BRT Recommendation

The EU and Japan should seek opportunities for partnerships between governments and research institutes to develop pre-competitive technologies for next-generation batteries (e.g., for lowering cost, improving battery life, enhancing safety, and raising energy density).

### Action taken so far

The Government of Japan (GOJ) has been conducting the national project of R&D for the achievement of more durable and safer battery with lower cost and more energy density. In particular, the GOJ is developing advanced materials, modules and systems for the purpose of enhancing lithium-ion batteries, and engages in a study toward the establishment of method to evaluate lifetime and to assess safety of them. In addition to that, the GOJ has embarked a study on innovative batteries that surpasses lithium-ion mbatteries (post- lithium-ion battery).

As for these projects, the relevant information is constantly shared with the researchers in the EU through discussion parties on battery that are regularly held in Japan.

### Future outlook

The GOJ will continue these R&D.

## 8. Sharing best practices for reuse and recycling of batteries (WP-E/#14/EJ to EJ)

### BRT Recommendation

The EU and Japan should share best practices with respect to the reuse and recycling of rechargeable batteries to enhance their secondary use.

### Action taken so far

The JBRC (Japan Portable Rechargeable Battery Recycling Center), which consists of manufacturers of portable rechargeable batteries and apparatus using them and importers of rechargeable batteries, was established by the Act on the Promotion of Effective Utilization of Resources in April 2001. The JBRC executes recycling of rechargeable batteries based on this law. Specially, the JBRC, collects portable recycling batteries from the facilities installed in recycle-supporting retail stores, municipal offices, and recycle-supporting entrepreneurs to promote recycling.

### Future outlook

The JBRC will continue to promote the recovery and recycling of portable rechargeable batteries.

The disposal of used lithium-ion rechargeable batteries is expected to grow in the future. On the other hand, in order to ensure the safety in the secondary use of used lithium-ion rechargeable batteries, it is necessary to develop environment such as the method to evaluate the state of deterioration of used lithium-ion rechargeable batteries. Therefore, taking account of the market trends emerging, it is necessary to consider both reuse and recycling of used lithium-ion rechargeable batteries in an integrated manner.

## 9. Further promoting demo projects of smart cities and smart grids (WP-E/#15/EJ to EJ)

### BRT Recommendation

The EU and Japan should further promote demonstration experiments of smart cities and smart grids with respect to rechargeable batteries and related products and should provide open access to allow each other's industry to participate in such experiments.

### < Background >

As an alternative energy with a stable energy supply, excellent economic potential, and zero CO<sub>2</sub> emissions nuclear energy is being reassessed by nations around the world. The serious accident at Fukushima's nuclear power plant, following the dramatic tsunami that struck Japan on 11 March 2011 also triggered a re-assessment of the safety measures and emergency response systems of nuclear power by all nations using or contemplating the use of nuclear energy.

### Rising Expectations for Nuclear Energy calls for a Strengthened Safety Framework

According to the Nuclear Energy Agency of the OECD (OECD-NEA), nuclear power accounted for 14% of global electricity production in 2009. This figure is expected to rise to 24% by 2050. As of January 2010, the International Atomic Energy Agency (IAEA) estimated that 437 nuclear power reactors were in operation worldwide, while a total of 56 reactors were under construction.

In the majority of the countries worldwide, there is still a growing interest in nuclear power generation to prevent dependence on fossil fuels, and a continuous stream of construction projects for nuclear power plants is underway. However, nuclear energy requires the highest safety standards. A lot has been done for several years at the national level, at the EU level, and at the international level (IAEA, Convention on Nuclear Safety). The industry has significantly improved the safety of its current reactor design. Now, the accident at Fukushima, caused by an extreme situation, demonstrates that safety must be continuously improved. As nuclear power will remain an attractive energy source for a large number of countries in the world (contribution to energy security and a low-carbon society), it is even more important to define world safety standards. The EU and Japan must play an active role in promoting and defining such standards.

While enhancing safety, it will be necessary to deal with the ageing of existing plants, improve facility utilization rates, and properly manage the nuclear fuel cycle (e.g., the management of used nuclear fuel). It will be essential to understand the mechanism of degradation of machinery and equipment as well as to conduct maintenance of ageing plants to maintain and restore their functions and performance. Therefore, the EU and Japan must promote, through international discussions like those held by the OECD-NEA, the exchange of information related to the technological assessment of ageing plants and to techniques associated with the appropriate maintenance of existing plants. As for the management of used fuel, the recovery and recycling of valuable materials remaining in used nuclear fuel will lead to the effective use of resources and reductions in radioactive waste.

### Rising Expectations for Rechargeable Batteries

Both the EU and Japan are developing next-generation lithium-ion rechargeable batteries. The

rechargeable battery is a potential key component in the development of smart grids worldwide, such as the “Smart City Project” in Japan, as well as a groundbreaking advanced application technology contributing to the promotion of renewable energy.

When used in a smart grid, rechargeable batteries can be placed at stations for large-scale photovoltaic or wind-power generation. They can also be installed in commercial districts and large-scale apartment housing complexes to store off-peak electricity.

Rechargeable batteries are used in the electric and plug-in hybrid vehicles being developed and promoted by Japanese and European car manufacturers. European and Japanese industry is actively seeking to improve the performance and cost of next-generation vehicle batteries to enable the more widespread use of EVs and PHVs.

The commercialization of next-generation electrically charged vehicles, including fuel-cell vehicles, will contribute to the conservation of energy, as well as a reduction in CO<sub>2</sub> emissions. To facilitate their market acceptance, the EU and Japan should cooperate on developing internationally harmonized requirements for the type approval and safety of electrically charged vehicles and common standards for accessing the battery-charging infrastructure. The objective should be to ensure that electric vehicles can be charged everywhere, at all times.

#### Action taken so far

In Japan, under an open access situation, not only Japanese companies but also foreign companies have been conducting demonstration experiments using renewable energy, rechargeable batteries and energy management system in four areas, Yokohama city, Toyota city, Kyoto Keihanna district and Kitakyushu city, which had been chosen for the “Demonstration Project on Next-generation Energy and Social Systems” since 2011. In 2012, experiments of demand response have been conducted in Toyota city, Kyoto Keihanna district and Kitakyushu city.

In order to complement this project, “Demonstration Project on Next-generation Energy technology” which demonstrates advanced or regionally specific technology has also been conducted on 8 sites in 2012.

#### Future outlook

Demonstration experiments of energy management will be continued by using smart grid system such as photovoltaic power systems, rechargeable batteries, smart meters, HEMS, BEMS, and CEMS in the four sites of “Demonstration Project on Next-generation Energy and Social Systems.”

“Demonstration project on Next-generation Energy technology” on 8 sites will be carried on.

In addition, another demonstration experiment will be conducted in terms of expected problems regarding telecommunication network including overcrowding and traffic delay, which may emerge upon deployment of Smart Grid.



## 10. Establishing a new, fair and effective international framework (WP-E/#16/EJ to EJ)

### BRT Recommendation

The EU and Japan should promote a post-Kyoto framework that engages all major emitters of greenhouse gases to take a fair share of the burden of global  $CO_2$  emission stabilization and reduction.

### Action taken so far

Japan has actively been contributing to negotiations at the Ad Hoc Working Group on the Durban Platform for Enhanced Action (ADP) which was established in the 17<sup>th</sup> Conference of Parties to the UNFCCC (COP17), with a view to establishing a fair and effective international framework applicable to all Parties. In the 18<sup>th</sup> Conference of Parties to the UNFCCC (COP18) held in Doha at the end of 2012, decisions were made on the arrangements for negotiations in the ADP from next year onwards. As a result, Japan has achieved its goal in COP18 of sending a message that “basic arrangements for negotiations have been set up toward an agreements by 2015 on a new legal framework beyond 2020”.

### Future outlook

Japan will actively continue to contribute to negotiations, through UNFCCC process, various international conferences and bilateral meetings, aiming at complete its work as early as possible but no later than 2015 in order to adopt a protocol, another legal instrument or an agreed outcome with legal force applicable to all Parties and to enable the outcome to come into effect and be implemented from 2020 in accordance with the work plan agreed in Doha.

11. Continuously improving incentives and regulations to promote and adoption of energy-efficient technologies and processes (WP-E/#20/EJ to EJ)

#### BRT Recommendation

The EU and Japan should continue to refine their regulations and incentives to promote the efficient use of energy (energy efficiency as well as energy savings). Setting mandatory principles for standards for building and house insulation plays a major role in reducing energy consumption and dependency and in achieving a significant reduction in CO2 emissions. Japan and the EU should also share best practices to implement energy efficiency regulations, Innovation processes, trainings, experimental programmes of construction and renovation regarding products and services.

#### < Background >

In the current context of economic crisis and increase of primary energy prices, energy efficiency and energy savings measures are the solution. An efficient use of energy is necessary for better fighting global warming, for reducing energy demand and consumption, energy dependency and for eliminating energy wastage. There is an important potential for reducing consumption in energy-intensive sectors such as manufacturing and transport, and even more significantly in the building sector. According to the International Energy Agency, residential, commercial and public buildings account for 30 to 40% of the world's energy consumption (and in each country too) and for 25 to 35% of the current world's CO2 emissions. Huge energy efficiency improvements can be expected in this sector if authorities take appropriate measures, such as adopting high level and binding standards, implementing building renovation programmes, coherent financing strategy for promoting energy efficiency, setting binding targets, ensuring compliance of energy efficiency related legislation, promoting training programmes and information regarding energy efficiency initiatives.

#### Action taken so far

Japanese energy efficient and conservation policy consists of both regulation and supportive measures which apply to industry, transportation, and the residential and commercial building sectors. The former is "Energy Conservation Law", and the latter is budgets, tax incentive, and so on.

Regarding residences and buildings, the Government of Japan (GOJ) has set energy saving standards including heat insulating performance. In July 2012, the GOJ decided the road map to 2020, to oblige all new residences and buildings step by step to conform to the energy conservation standard.

In addition, in December 2012, the GOJ has set low carbon standard for residences and buildings, to induce higher criteria of green residences and buildings compared to energy efficiency standards.

Furthermore, the GOJ has taken measures called "Top runner program" to improve energy efficiency of household appliances and automobiles. We often exchange information with other countries in international conferences.

#### Future outlook

Regarding residences and buildings, conformity to the energy saving standards will be made obligatory in stages for all newly built residences and buildings by 2020, sufficiently taking into account the necessity, degree, balance etc. of regulations.

The GOJ will add certain equipment and review energy efficiency standards in top runner program. Then we will share our information of energy efficiency and conservation policies positively.

## 12. Promoting adhesion and enforcement of EITI (WP-E/#21/EJ to EJ)

### BRT Recommendation

The EU and Japan should work closely with other governments, industrial bodies, and NGOs to enable resource-producing countries to fulfil the EITI's "Principles and Criteria" and to advance from candidate to compliant EITI countries.

### Action taken so far

Since the GOJ announced its decision to become a supporting country of the EITI in February 2009, it has proactively supported the EITI activities through various measures such as hosting an EITI outreach seminar titled "Emerging Trend Responsible Natural Resources Development" in Tokyo in January 2010 with participation of other governments, business people, NGO and others. In addition, the GOJ provided financial assistance for the first time to the EITI Multi Donor Trust Fund (MDTF) in FY2011. Moreover, The GOJ has continuously engaged in further promoting the EITI in the framework of G8/G20.

### Future outlook

The GOJ will provide financial assistance to the EITI Multi Donor Trust Fund (MDTF) this fiscal year. Also, the GOJ continues to consider means to provide further cooperation for the EITI and positively supports the EITI activities of implementing countries and outreach countries.

### 13. Promoting action to minimize commodity price volatility (WP-E/#22/EJ to EJ)

#### BRT Recommendation

Japan and the EU should strive to reduce excessive price volatility in commodity markets and should accordingly identify common actions to take in international fora.

#### Action taken so far

In international conferences such as the International Energy Forum (IEF), the Asian Ministerial Energy Roundtable Meeting, G20, price volatility of fossil fuels has been discussed. In the 13th IEF Ministerial Meeting held on March 2012, the Government of Japan (GOJ): 1) pointed out that it is necessary for producing countries to behave responsibly toward the stabilization of the energy supply for the market stability, 2) commented that GOJ will contribute actively to the continuous effort to strengthen the market stability and the producer-consumer dialogue, throughout the additional contribution from GOJ for the improvement of market transparency, and for the further development and the expansion to natural gas in JODI. Additionally the GOJ, as a member of the International Organization of Securities Commissions (IOSCO), conducted the survey on implementation of “the Principles for the Regulation and Supervision of Commodity Derivatives Markets” which was published in September 2011 for improving transparency, regulation and supervision and addressing market abuses and manipulation in commodity derivative markets, and also set out “the Principles for the Oil Price Reporting Agencies” for the purpose of reliability enhancement in figuring out the pricing by Oil Price Reporting Agencies.

#### Future outlook

Japan continues to tackle stabilizing fossil fuel price through various international conferences. Additionally, we will work in IOSCO to assess the impact of “the Principles for the Oil Price Reporting Agencies” on physical markets and to prepare a progress report on the implementation of the principles in 2013.

#### 14. Supporting R&D for recycling and material substitution (WP-E/#23/EJ to EJ)

##### BRT Recommendation

Japan and the EU should encourage the recycling of raw materials in developed countries through R&D, industrial policy, and international cooperation as well as promote research aimed at the substitution of critical raw materials.

##### < Background >

The rising cost, price volatility, and unstable supply of raw materials are a concern for Europe and Japan business. The policies of resource-rich countries can alleviate or exacerbate such a concern. Stable access to rare metals is critical to expanding the production of rechargeable batteries, as well as to several other industries. There are diversified sources of supply of positive-electrode materials such as lithium, manganese, cobalt, and nickel used for rechargeable batteries. However, some other rare earths are currently only available from China. The EU and Japan should reinforce their efforts to diversify their sources of supply and to secure a stable supply of rare metals.

##### The Escalation of International Competition

The rapidly growing demand for energy and natural resources mainly comes from developing countries, notably China and India. International competition to secure energy and natural resources is intensifying. Moreover, raw-material and energy-access diplomacy has been on the rise and has the potential to distort markets. The inflow of financial funds has contributed to the price volatility of major mineral resources. The mining regulations and trade policies of the resource-rich countries can heavily influence the availability and price of some raw materials. All these developments put pressure on the competitiveness and stable and profitable development of Japanese and European industry. Rapidly rising raw material prices could adversely affect corporate profits and the world economic recovery. Commodity-price volatility in the agricultural sector is also a threat to global growth and food security.

##### Responsible Development of Natural Resources

The “Extractive Industries Transparency Initiative” (EITI) adopted at the “World Summit for Sustainable Development” in Johannesburg in 2002 sought to promote the responsible development of natural resources by increasing the transparency of payments made by companies to government and government-linked entities in the extractive sectors. With good governance, these natural resources can generate large revenues that governments of resource-rich countries can use to foster economic recovery and reduce poverty. However, when governance is weak, revenues may be squandered, creating a downward spiral of poverty, corruption, conflict, and the unsustainable development of minerals and resources. As of November 2010, only five countries were EITI-compliant, and 28 others had achieved

EITI-candidate status. In several other countries, there are concerns that the revenue generated by natural resources is funnelled to funding conflicts. European and Japanese business can support the EITI objectives by implementing the open and responsible supply-chain management of resources. At the government level, the EU and Japan should pursue common strategies to keep energy and

mineral markets open, undistorted, and stable.

#### Action taken so far

Following the large-scale reduction of the export quotas of Chinese rare earth in 2010, the Government of Japan promotes cooperation with consuming countries such as with the EU, in order to secure raw materials including rare metals.

The Second Trilateral EU-Japan-U.S. Conference on Critical Materials for a Clean Energy Future was held in Tokyo on March 28-29, 2012, following the First Trilateral Conference held in Washington DC in October 2011. At this conference, EU, Japan and the U.S. shared the recognition of the importance of working on the development of alternative materials and technologies for reducing usage and recycling under the cooperation among consuming countries.

#### Future outlook

The 3rd Trilateral EU-Japan-U.S. Conference will be held in Brussels in May 2013. “Recycling of rare metals” will be proposed as one of the themes of the conference.

Tax-system-related proposals

In 14<sup>th</sup> EU-Japan Business Round Table, the followings were proposed with respect to Japanese tax system:

Working Party D:

2. Tax issue proposal for Japan

- (1). Review 2012 tax reform
- (2). Review of transfer-price taxation
- (3). Tax authorities to accept and process applications for tax rulings and tax law.

Changes to the Japanese tax system are made every year, and the decisions on what changes to make are made following deliberations by bodies such as the government's Tax Commission. These deliberations focus on requests and opinions submitted by government ministries and agencies to the tax authorities, and take into account the economic climate, fiscal situation. Opinions from various levels, including proposals from the Business Round Table, are referred to by ministries and agencies when they prepare their requests for changes to the tax system, and appropriately reflected in the tax reform process.